

PRESERVE ACCESS TO AFFORDABLE GENERICS AND BIOSIMILARS ACT

DECEMBER 24, 2020.—Committed to the Committee of the Whole House on the State
of the Union and ordered to be printed

Mr. NADLER, from the Committee on the Judiciary,
submitted the following

R E P O R T

together with

ADDITIONAL VIEWS

[To accompany H.R. 2375]

[Including cost estimate of the Congressional Budget Office]

The Committee on the Judiciary, to whom was referred the bill (H.R. 2375) to prohibit prescription drug companies from compensating other prescription drug companies to delay the entry of a generic drug, biosimilar biological product, or interchangeable biological product into the market, having considered the same, reports favorably thereon without amendment and recommends that the bill do pass.

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Purpose and Summary

H.R. 2375, the “Preserve Access to Affordable Generics and Biosimilars Act,” is designed to address the soaring cost of prescription drugs by targeting reverse-payment patent settlement agreements (“reverse-payment agreements”), also referred to as “pay-for-delay” agreements. Reverse-payment agreements occur when a pharmaceutical drug company pays a competitor to keep a generic (or biosimilar) version of its drug off the market as part of a patent settlement agreement. These deals delay access to more affordable generic (or biosimilar) versions of the drugs, costing consumers and the government billions of dollars in higher drug costs. H.R. 2375 is supported by a coalition of healthcare providers, patient groups, and public-interest organizations including AARP, Consumer Reports, Public Citizen, Patients for Affordable Drugs Now, Premier Inc. Healthcare Alliance, and the American Academy of Dermatology Association.

Background and Need for the Legislation

BACKGROUND

Reverse payment patent settlements arise in the context of patent litigation between pharmaceutical drug companies. These financial arrangements often take the form of a patent litigation settlement agreement in which the branded drug firm pays its potential generic competitor to settle patent claims and delay entering the market with a lower-cost generic product. Notably, such agreements could also occur between manufacturers of biologic or biosimilar drugs, or manufacturers of competing generic (or biosimilar) products. According to a Federal Trade Commission (FTC) report in 2010, pay-for-delay agreements were estimated to cost American consumers \$3.5 billion per year—\$35 billion over the decade from 2010 to 2020.¹

The Role of Generic and Biosimilar Competition in Lowering Prescription Drug Costs

Pay-for-delay agreements seek to block or delay price-reducing generic and biosimilar entry. Because generic competition is critical to reducing the high cost of prescription drugs this conduct is particularly harmful. Generic drugs typically cost 80 to 85% less than their brand-name alternatives.² Lower-priced generic drugs saved the U.S. health care system about \$1.7 trillion from 2007 to 2016.³ Because of the universal recognition that generic competition is beneficial for patients and taxpayers, Congress and state legislatures have enacted legislation to facilitate the ability of drug makers to bring generic and biosimilar prescription drug products to market.

The Federal Food, Drug, and Cosmetic Act (FDCA),⁴ as amended by the Drug Price Competition and Patent Term Restoration Act of

¹ FED. TRADE COMM’N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 2 (2010), <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>.

² *Generic Drugs: Questions & Answers*, U.S. FOOD & DRUG ADMIN. (2018), <https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers>.

³ *Id.*

⁴ 21 U.S.C. § 301 (2019).

1984 (Hatch-Waxman Act)⁵ and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,⁶ has established procedures to facilitate competition from lower-priced generic drug manufacturers, while maintaining incentives for branded drug manufacturers to invest in developing new drugs.

Biologics are governed by the Biologics Price Competition and Innovation Act (BPCIA), rather than the Hatch-Waxman Act.⁷ Similar to the Hatch-Waxman Act, the BPCIA establishes procedures to facilitate competition from drug manufacturers of lower-priced biosimilars (or interchangeables), while maintaining incentives for branded drug manufacturers to invest in developing new biological drug products.

The Hatch-Waxman Act has succeeded in facilitating generic competition and generating large savings for patients, health care plans, and federal and state governments. Among other provisions, the Act includes a mechanism for accelerated approval of generic drugs through an Abbreviated New Drug Application (ANDA) process. Although the BCPIA is relatively new, the legislation has facilitated biosimilar competition to expensive biologic products, also resulting in savings.

Due to these significant price advantages and cost savings, many third-party payers for prescription drugs—health insurance plans and Medicaid programs—have adopted policies to encourage the substitution of generic drugs for their branded counterparts. In addition, all fifty states and the District of Columbia have drug substitution laws that encourage and facilitate the substitution of lower-cost generic drugs for branded drugs. Consequently, generic drugs typically capture over 80% of a branded drug's share of unit and dollar sales within six months of market entry.⁸ Meanwhile, according to a 2016 *Journal of the American Medical Association* analysis, 72% of drug spending comes from just 10% of brand-name medications.⁹ Consequently, there is significant money at stake in the battle between branded and generic drug manufacturers.

The Statutory Framework in Which Pay-for-Delay Agreements Arise

The patent litigation that gives rise to these types of agreements usually occurs within the framework that the Hatch-Waxman Act established for generic entry.¹⁰ Under Hatch-Waxman, a generic competitor may seek entry before the expiration of a brand-name drug's patents. To seek Food and Drug Administration (FDA) approval for entry before the patents expire, a generic must declare that its product does not infringe the relevant patents or that the

⁵*Id.* at § 355.

⁶*Id.* at § 355(b)(2), (j); 35 U.S.C. § 271(e) (2019).

⁷See Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111–148, 124 Stat. 119,804 (2010) (codified as amended in scattered sections of the U.S. Code) (BPCIA was enacted under Title VII of PPACA).

⁸*Generics Grab 80% Share of US Market and Fill 78% of Prescriptions*, GENERICS AND BIOSIMILARS INITIATIVE (May 13, 2011), <http://gabionline.net/Reports/Generics-grab-80-share-of-US-market-and-fill-78-of-prescriptions>. (citing a report published by IMS Health in April 2011); see also U.S. DEP'T OF HEALTH AND HUMAN SERVS., "SOME OBSERVATIONS RELATED TO THE GENERIC DRUG MARKET 4" (2015), https://aspe.hhs.gov/system/files/pdf/139331/ib_GenericMarket.pdf (on average the generic product captures 90% of the market within one year of entry).

⁹Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 J. A. MED. ASS'N 858, 860 (2016), <https://phhp-bahealthscience-new.sites.medinfo.ufl.edu/files/2016/09/jsc1600151.pdf>.

¹⁰The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (2019)) (governing how generics may enter the marketplace to compete with brand-name pharmaceuticals).

patents are invalid.¹¹ Branded drug companies often challenge the generic's declaration, resulting in litigation between the brand-name and generic drug makers to determine whether the patents at issue are valid or infringed. This is often referred to as ANDA litigation because it arises under the FDA's Abbreviated New Drug Application (ANDA) process. Hatch-Waxman incentivizes generics to challenge the branded company's patents, and risk ANDA litigation, because the Act provides that the first generic to file its application can obtain a 180-day period of market exclusivity—during which it is the only generic on the market.¹² For the brand-name company to win the ANDA litigation and block generic entry, it must defend the validity of its patents and show that the generic's product would infringe those patents.

Because of the expense and uncertain outcome of patent litigation, brand-name and generic pharmaceutical companies sometimes settle the litigation before a court reaches a final decision. In the absence of compensation to the generic for delaying its entry, it is unlikely that these settlement agreements would raise antitrust issues.¹³

Due to the significant loss of market share and profits that branded manufacturers experience upon entry of generic competitors, however, some of these settlement agreements are anti-competitive, involving brand-name drug companies committing to pay the generic manufacturer a fee to delay the marketing of its generic version of the drug for a given period of time. Markus Meier, who leads the FTC's health care division and previously served as Acting Director of the FTC's Bureau of Competition, testified last Congress that “[b]randed manufacturers have used such agreement [sic] to buy more protection from competition than their patent rights provide, at the expense to competition and consumers.”¹⁴ A recent FTC opinion explained why these pay-for-delay agreements are also referred to as “reverse payment” settlements:

In a reverse payment settlement, the branded drug maker—the *plaintiff* in the patent infringement action—pays the patent challenger and alleged infringer—the *defendant*—to refrain from offering its generic drug for a period of time as part of a settlement of patent litigation. The value in the settlement flows in the opposite direction of what one would ordinarily expect, where the defendant and alleged infringer might pay the plaintiff intellectual property (IP) rights holder for allegedly violating those rights.¹⁵

Since 2001, the FTC has filed a number of successful lawsuits to stop pay-for-delay settlements due to these significant anti-com-

¹¹ 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2019).

¹² *Id.* at § 355(j)(5)(B)(iv).

¹³ See Fed. Trade Comm'n v. Actavis, Inc., 570 U.S. 136, 158 (2013) (“[T]he fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit. They may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point.”).

¹⁴ *Antitrust Concerns and the FDA Approval Process: Hearing Before the Subcomm. on Regulatory Reform, Commercial, and Antitrust Law of the H. Comm. on the Judiciary*, 115th Cong. (2017) (written testimony of Markus Meier, Acting Director, Bureau of Competition, Fed. Trade Comm'n, at 15), <https://republicans-judiciary.house.gov/wp-content/uploads/2017/07/Meier-FTC-Testimony.pdf>.

¹⁵ In re Impax Labs., Inc., No. 9373, at 2 (F.T.C. Mar. 28, 2019).

petitive effects. Its efforts resulted in the Supreme Court’s 2013 landmark decision in *FTC v. Actavis*, which held that these settlements are subject to antitrust scrutiny.¹⁶ Following this decision, the number of these potentially anti-competitive deals has fallen, but a significant number have continued to occur. The total number of such settlements filed with the FTC has dropped to 21 in FY 2014 from 29 in FY 2013, and 40 in FY 2012 prior to the *Actavis* ruling.¹⁷ In the FTC’s 2017 report assessing final Hatch-Waxman patent settlements—the most recent report available—the agency identified 20 final settlements that contained explicit compensation to the generic company and a restriction on selling a generic product for a period of time.¹⁸

NEED FOR THE LEGISLATION

H.R. 2375 is necessary to put an end to pay-for-delay settlements. These agreements cause significant consumer harm by imposing increased costs for prescription drugs on patients and taxpayers. Despite the FTC’s landmark victory in 2013 at the Supreme Court in *Actavis*, pharmaceutical companies continue to engage in pay-for-delay agreements. In the years since *Actavis*, lawsuits challenging pay-for-delay agreements continued to take up a large amount of the FTC’s time and resources.¹⁹ Furthermore, given that judges in some post-*Actavis* cases appear to have misinterpreted or ignored key aspects of the Supreme Court’s decision,²⁰ the “Preserve Access to Affordable Generics and Biosimilars Act,” is a vital piece of legislation to prevent backsliding by the courts that may result in uncertainty, enforcement difficulties, or result in a less competitive landscape altogether.

Pay-for-Delay Agreements Result in Higher Prescription Drug Costs and Significant Harm to Patients

When pharmaceutical companies delay entry of generic or biosimilar drugs through pay-for-delay agreements, they deprive consumers of the lower prices that generic and biosimilar competition brings to the market. For some consumers, these delays could mean the difference between life and death. As a result of soaring prices, many patients skip doses, take less than the prescribed

¹⁶ Fed. Trade Comm’n v. *Actavis, Inc.*, 570 U.S. 136, 158 (2013) (holding that a “reverse payment” settlement agreement, “where large and unjustified, can bring with it the risk of significant anticompetitive effects”).

¹⁷ See Press Release, Fed. Trade Comm’n, FTC Report on Drug Patent Settlements Shows Potential Pay-for-Delay Deals Decreased Substantially in the First Year Since Supreme Court’s *Actavis* Decision (Jan. 13, 2016), <https://www.ftc.gov/news-events/press-releases/2016/01/ftc-report-drug-patent-settlements-shows-potential-pay-delay>.

¹⁸ See Press Release, Fed. Trade Comm’n, FTC Staff Issues FY 2017 Report on Branded Drug Firms’ Patent Settlements with Generic Competitors (Dec. 3, 2020), https://www.ftc.gov/news-events/press-releases/2020/12/ftc-staff-issues-fy-2017-report-branded-drug-firms-patent?utm_source=govdelivery.

¹⁹ See *Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets: Hearing Before the Subcomm. on Antitrust, Commercial, and Admin. Law of the H. Comm. on the Judiciary*, 116th Cong. (2019) (written testimony of Michael Kades, Director of Markets and Competition, at 2), <https://docs.house.gov/meetings/JU/JU05/20190307/109024/HHRG-116-JU05-Bio-KadesM-20190307.pdf>.

²⁰ *Id.*; Michael A. Carrier, *The Curious Case of Wellbutrin: How the Third Circuit Mistook Itself for the Supreme Court*, 103 CORNELL L. REV. ONLINE 137, 145 (2018) (stating that the Third Circuit’s ruling in *Wellbutrin* “cannot be reconciled” with the Supreme Court’s holding in *Actavis*).

amount of medicine, or do not fill their prescriptions.²¹ According to a study by Kaiser Health News, “[h]undreds of thousands of cancer patients are delaying care, cutting their pills in half or skipping drug treatment entirely.”²²

As several leading experts have noted, these delay tactics can be enormously profitable for drug manufacturers.²³ Michael Kades, the Director of Markets and Competition Policy at the Washington Center for Equitable Growth, testified this Congress that “delaying competition on a blockbuster drug for just a year can mean hundreds of million[s], if not billions of dollars in additional profit.”²⁴ Furthermore, in the absence of a strong deterrent, “many companies will see antitrust liability simply as a cost of doing business.”²⁵

The Supreme Court’s Actavis Decision Did Not Solve the Problem

Although there has been significant progress toward eliminating reverse payment agreements in the wake of the Supreme Court’s decision in *Actavis*, this ruling did not entirely resolve the problem. As Dr. Aaron Kesselheim of Harvard Medical School testified before the Subcommittee last Congress:

[T]he *Actavis* case was really about . . . settlements that included extremely large monetary transfers like handing over of suitcases full of cash. But since then, pay-for-delay settlements have continued. Many of them also still involve monetary settlements. But many of them also now involve more complex co-marketing arrangements or other kinds of business deals . . . and these kinds of agreements persist.²⁶

Lawsuits challenging pay-for-delay agreements continue to take up a large amount of time and resources. For example, last year marked the ten-year anniversary of when the FTC filed its original complaint in *Actavis*.²⁷ After over a decade, however, the FTC announced that it reached a settlement with the last remaining de-

²¹ Liz Szabo, *Sticker Shock Forces Thousands of Cancer Patients To Skip Drugs, Skimp On Treatment*, KAISER HEALTH NEWS (Mar. 15, 2017), <https://khn.org/news/sticker-shock-forces-thousands-of-cancer-patients-to-skip-drugs-skimp-on-treatment>.

²² *Id.*

²³ See, e.g., *Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets: Hearing Before the Subcomm. on Antitrust, Commercial, and Admin. Law of the H. Comm. on the Judiciary*, 116th Cong. (2019).

²⁴ *Id.* (testimony of Michael Kades, Director of Markets and Competition Policy, Washington Center for Equitable Growth), available at <http://www.cq.com/doc/congressionaltranscripts-5482270?2>; see also *In re Impax Labs., Inc.*, No. 9373, at 7 (F.T.C. Mar. 28, 2019) (“Endo forecast that, if Impax launched its generic at risk, Endo would lose 85 percent of its branded Opana ER sales within three months, and \$100 million in sales revenue within six months.”).

²⁵ *Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets, Hearing Before the Subcomm. on Antitrust, Commercial, and Admin. Law of the H. Comm. on the Judiciary*, 116th Cong. (2019) (written testimony of Michael Kades, Director of Markets and Competition Policy, Washington Center for Equitable Growth, at 1), <https://docs.house.gov/meetings/JU/JU05/20190307/109024/HHRG-116-JU05-Bio-KadesM-20190307.pdf>.

²⁶ *Antitrust Concerns and the FDA Approval Process: Hearing Before the Subcomm. on Regulatory Reform, Commercial, and Antitrust Law of the H. Comm. on the Judiciary*, 115th Cong. 32–34 (2017) (testimony of Aaron S. Kesselheim, M.D., M.P.H., Associate Professor of Medicine, Harvard Medical School), <https://republicans-judiciary.house.gov/wp-content/uploads/2017/07/115-27.pdf>.

²⁷ Complaint, Fed. Trade Comm’n v. Watson Pharm., Inc., No. 09–00598 (C.D. Cal. Jan. 29, 2009), https://www.ftc.gov/sites/default/files/documents/cases/2009/02/090202androgelcmpt_0.pdf.

fendant.²⁸ As Mr. Kades of the Washington Center for Equitable Growth testified:

Despite the U.S. Supreme Court's clear signal in the *Actavis* case that pay-for-delay can be anticompetitive, the FTC continues to spend substantial resources and time challenging clear violations. Tougher laws, such as the Preserve Access to Affordable Generics Act, would deter such conduct and free up limited resources to attack other anticompetitive conduct.²⁹

Additionally, judges in some post-*Actavis* cases appear to have misinterpreted or ignored key aspects of the Supreme Court's decision. For example, a number of commentators have pointed out that in *In re Wellbutrin XL Antitrust Litigation*,³⁰ the Third Circuit departed from the Supreme Court's reasoning in *Actavis* as it upheld the lower court's dismissal of an antitrust claim based on a reverse payment settlement.³¹ In reaching its decision, the Third Circuit stated that it was persuaded by a defense³² specifically rejected by the Supreme Court in *Actavis*, namely that "risk aversion" could justify a branded drug company's settlement payment to a potential generic competitor.³³ Accordingly, the *Wellbutrin* decision may invite defendants in pay-for-delay cases to hide behind a defense the Supreme Court has already rejected—that a large reverse payment may be justified on the basis of the brand-name company's aversion to risk. Such backsliding is inconsistent with the principle of stare decisis, raises hurdles to effective enforcement, and creates uncertainty for litigants. The "Preserve Access to Affordable Generics and Biosimilars Act" is necessary to prevent courts from backsliding. H.R. 2375 makes clear that the defenses that the Supreme Court rejected in *Actavis*, including the avoidance of risk and desire for certainty, are not available to defendants as a justification for an otherwise illegal reverse-payment agreement.

H.R. 2375 Is an Effective Solution to Anti-Competitive Pay-for-Delay Agreements

The "Preserve Access to Affordable Generics and Biosimilars Act" strengthens the FTC's ability to challenge anti-competitive pay-for-

²⁸ See Press Release, Fed. Trade Comm'n, Last Remaining Defendant Settles FTC Suit that Led to Landmark Supreme Court Ruling on Drug Company "Reverse Payments" (Feb. 28, 2019), <https://www.ftc.gov/news-events/press-releases/2019/02/last-remaining-defendant-settles-ftc-suit-led-landmark-supreme>.

²⁹ *Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets*, Hearing Before the Subcomm. on Antitrust, Commercial, and Admin. Law of the H. Comm. on the Judiciary, 116th Cong. (2019) (written testimony of Michael Kades, Director of Markets and Competition Policy, Washington Center for Equitable Growth, at 2), <https://docs.house.gov/meetings/JU/JU05/20190307/109024/HHRG-116-JU05-Bio-KadesM-20190307.pdf>.

³⁰ 868 F.3d 132 (3d Cir. 2017).

³¹ See, e.g., Michael A. Carrier, *The Curious Case of Wellbutrin: How the Third Circuit Mistook Itself for the Supreme Court*, 103 CORNELL L. REV. ONLINE 137, 145 (2018) (stating that the Third Circuit's ruling in *Wellbutrin* "cannot be reconciled" with the Supreme Court's holding in *Actavis*); Br. for the Nat'l Ass'n of Chain Drug Stores, Inc. as Amicus Curiae Supporting Appellants at 2, *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132 (3d Cir. 2017) ("[T]he Panel's opinion resuscitated the risk aversion explanation for reverse payments that *Actavis* definitively rejected.").

³² *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 168 (3d Cir. 2017).

³³ See Michael A. Carrier, *The Curious Case of Wellbutrin: How the Third Circuit Mistook Itself for the Supreme Court*, 103 CORNELL L. REV. ONLINE 137, 145 (2018) (explaining that the *Wellbutrin* court "resuscitated the defense based on risk aversion that the Supreme Court had rejected").

delay agreements in court. By establishing that pay-for-delay agreements that keep lower-priced generics from entering the market are presumptively illegal under antitrust law, H.R. 2375 will result in lower drug prices for consumers. This bill strikes the right balance by deterring drug companies from reaching anti-competitive settlements while allowing them to pursue agreements that do not harm competition.

Hearings

In the 116th Congress, the Subcommittee on Antitrust, Commercial, and Administrative Law held a hearing on “Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets.”³⁴ At this hearing, several witnesses testified about competition issues in health care markets, including Dr. Fiona Scott Morton, Professor of Economics at Yale School of Management; Dr. Martin Gaynor, Professor of Economics and Health Policy at Carnegie Mellon University; Michael Kades, Director of Markets and Competition Policy at Washington Center for Equitable Growth; and Dr. Craig Garthwaite, Herman R. Smith Research Professor at Northwestern University’s Kellogg School of Management. At this hearing, both Dr. Scott Morton³⁵ and Mr. Kades³⁶ identified pay-for-delay settlements as an ongoing problem, and each testified about the need for congressional action in this area. This hearing satisfies the requirement of H. Res. 6, sec. 103(i).

Last Congress, the Subcommittee held a hearing on “Antitrust Concerns and the FDA Approval Process.”³⁷ On the first panel, the Subcommittee heard testimony from Dr. Scott Gottlieb, Commissioner of the FDA, and Mr. Markus Meier, Acting Director, Bureau of Competition. On the second panel, the Subcommittee heard testimony from Professor David Olson, Boston College Law School; Professor Erika Lietzan, University of Missouri School of Law; Mr. Alden Abbott, Deputy Director and Senior Legal Fellow, the Heritage Foundation; and Professor Aaron Kesselheim, M.D. M.P.H., Harvard Medical School. During the hearing, Acting Director Meier³⁸ and Professor Kesselheim³⁹ each testified that pay-for-delay agreements inhibit competition in health care markets and remain an ongoing problem.

Committee Consideration

On April 30, 2019, the Committee met in open session and ordered the bill, H.R. 2375, favorably reported by unanimous voice vote, a quorum being present.

³⁴*Id.*

³⁵*Id.* (written testimony of Fiona Scott Morton, Professor of Economics, Yale School of Management, at 3), <https://docs.house.gov/meetings/JU/JU05/20190307/109024/HHRG-116-JU05-Wstate-MortonF-20190307.pdf>.

³⁶*Id.* (written testimony of Michael Kades, Director of Markets and Competition, Washington Center for Equitable Growth, at 2), <https://docs.house.gov/meetings/JU/JU05/20190307/109024/HHRG-116-JU05-Bio-KadesM-20190307.pdf>.

³⁷*Antitrust Concerns and the FDA Approval Process: Hearing Before the Subcomm. on Regulatory Reform, Commercial, and Antitrust Law of the H. Comm. on the Judiciary*, 115th Cong. (2017), <https://republicans-judiciary.house.gov/wp-content/uploads/2017/07/115-27.pdf>.

³⁸*Id.* at 10–11 (testimony of Markus Meier, Acting Director, Bureau of Competition, Federal Trade Commission).

³⁹*Id.* at 32–34 (testimony of Aaron S. Kesselheim, Associate Professor of Medicine, Harvard Medical School).

Committee Votes

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the Committee advises that no rollcall votes occurred during the Committee's consideration of H.R. 2375.

Committee Oversight Findings

In compliance with clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee advises that the findings and recommendations of the Committee, based on oversight activities under clause 2(b)(1) of rule X of the Rules of the House of Representatives, are incorporated in the descriptive portions of this report.

New Budget Authority and Tax Expenditures

Clause 3(c)(2) of rule XIII of the Rules of the House of Representatives is inapplicable because this legislation does not provide new budgetary authority or increased tax expenditures.

Congressional Budget Office Cost Estimate

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the Committee sets forth, with respect to the bill, H.R. 2375, the following estimate and comparison prepared by the Director of the Congressional Budget Office under section 402 of the Congressional Budget Act of 1974:

H.R. 2375, Preserve Access to Affordable Generics and Biosimilars Act			
As ordered reported by the House Committee on the Judiciary on April 30, 2019			
By Fiscal Year, Millions of Dollars	2019	2019-2024	2019-2029
Direct Spending (Outlays)	0	-193	-520
Revenues	0	34	93
Deficit Effect	0	-227	-613
Spending Subject to Appropriation (Outlays)	0	-24	n.e.
Pay-as-you-go procedures apply?	Yes	Mandate Effects	
Increases on-budget deficits in any of the four consecutive 10-year periods beginning in 2030?	No	Contains intergovernmental mandate?	No
		Contains private-sector mandate?	Yes, Over Threshold
n.e. = not estimated.			

H.R. 2375 would make certain agreements—used to settle claims of patent infringement between sponsors of brand-name, generic, or biosimilar drugs and relating to the sale of a drug or biological product—presumptively illegal under antitrust law. The bill would require particular types of agreements arising from proceedings conducted by the Patent Trial and Appeal Board (PTAB) to be reported to Federal Trade Commission (FTC) and the Department of Justice (DOJ). H.R. 2375 also would establish the authority to impose civil penalties when a party to a settlement is found to have violated the bill's requirements.

CBO expects that the bill would accelerate the availability of lower-priced generic or biosimilar drugs that would have been affected by agreements targeted by the bill and reduce the average price of drugs paid by federal health programs that purchase drugs or provide health insurance that covers drugs. In total, CBO estimates that enacting H.R. 2375 would decrease the deficit by \$613 million over the 2019–2029 period. That amount includes a \$520 million reduction in direct spending and a \$93 million increase in revenues.

CBO also estimates that implementing H.R. 2375 would decrease spending subject to appropriation by \$24 million over the 2019–2024 period, assuming appropriation actions consistent with the bill. That decrease would result primarily because lower estimated drug prices would reduce costs for discretionary health programs.

Details of the estimated budgetary effect of H.R. 2375 are shown in Table 1. Those effects fall primarily within budget functions 370 (commerce and housing credit), 550 (health), and 570 (Medicare).

TABLE 1.—ESTIMATED BUDGETARY EFFECTS OF H.R. 2375

	By fiscal year, millions of dollars—												
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2019–2024	2019–2029
Decreases in Direct Spending													
Estimated Budget Authority	0	0	–21	–53	–63	–56	–58	–61	–65	–74	–69	–193	–520
Estimated Outlays	0	0	–21	–53	–63	–56	–58	–61	–65	–74	–69	–193	–520
On-Budget	0	0	–21	–53	–63	–56	–58	–61	–65	–74	–69	–192	–518
Off-Budget ^a	0	0	*	*	*	*	*	*	*	*	*	–1	–2
Increases in Revenues													
Estimated Revenues	0	0	3	9	11	11	10	11	12	12	13	34	93
On-Budget	0	0	3	6	8	8	7	8	9	9	10	25	69
Off-Budget ...	0	0	1	2	3	3	3	3	3	3	3	9	24
Net Decrease in the Deficit													
From Changes in Direct Spending and Revenues													
Effect on the Deficit	0	0	–24	–62	–74	–67	–68	–72	–77	–86	–82	–227	–613
On-Budget	0	0	–23	–59	–71	–64	–66	–69	–74	–83	–78	–217	–587
Off-Budget ...	0	0	–1	–3	–3	–3	–3	–3	–3	–3	–4	–10	–26
Increases or Decreases (–) in Spending Subject to Appropriation													
Estimated Authorization	0	*	–3	–6	–8	–7	n.e.	n.e.	n.e.	n.e.	n.e.	–24	n.e.
Estimated Outlays	0	*	–3	–6	–8	–7	n.e.	n.e.	n.e.	n.e.	n.e.	–24	n.e.

Components may not sum to totals because of rounding; n.e. = not estimated; * = between –\$500,000 and zero.

^a Includes off-budget effects on the operating costs of the U.S. Postal Service.

By enhancing FTC authority to restrict certain agreements between sponsors of brand-name, generic, or biosimilar drugs, H.R. 2375 would impose a private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA). The bill also would impose a private-sector mandate by requiring those manufacturers to notify the FTC of agreements that resolve PTAB proceedings. CBO estimates the cost of the mandate, particularly in the form of lost revenues, would exceed the threshold for private-sector mandates established in UMRA (\$164 million in 2019, adjusted annually for inflation) in at least two of the first five years the mandate is in effect.

On April 26, 2019, CBO transmitted an estimate for H.R. 1499, the Protecting Consumer Access to Generic Drugs Act of 2019, as ordered reported by the House Committee on Energy and Commerce on April 3, 2019. CBO's estimates of the effect on the deficit through 2029 for the two bills are the same. In different ways, both H.R. 2375 and H.R. 1499 would modify the conduct of enforcement actions by FTC against parties to certain agreements to settle a claim of patent infringement and would impose significant restrictions on the terms of compensation in affected agreements. H.R. 2375 also would require particular types of agreements relating to PTAB proceedings to be filed with FTC and the DOJ; H.R. 1499 does not contain a comparable provision. CBO expects that both bills would accelerate, on average, the availability of lower-priced generic and biosimilar drugs to a similar extent and would generate an equivalent amount of budgetary savings from 2020 through 2029.

The CBO staff contact for this estimate is Julia Christensen. The estimate was reviewed by Leo Lex, Deputy Assistant Director for Budget Analysis.

Duplication of Federal Programs

No provision of H.R. 2375 establishes or reauthorizes a program of the Federal government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

Performance Goals and Objectives

The Committee states that pursuant to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, H.R. 2375 would lower drug prices by ending abusive pay-for-delay settlements. By establishing that pay-for-delay agreements are presumptively illegal under antitrust law, the “Preserve Access to Affordable Generics and Biosimilars Act” will lower drug prices for consumers.

Advisory on Earmarks

In accordance with clause 9 of rule XXI of the Rules of the House of Representatives, H.R. 2375 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(d), 9(e), or 9(f) of rule XXI.

Section-by-Section Analysis

The following discussion describes the bill as reported by the Committee.

Section 1. Short Title. Section 1 sets forth the title of the legislation as the “Preserve Access to Affordable Generics and Biosimilars Act.”

Section 2. Declaration of Purposes. Section 2 sets forth the purposes of the Act as: (1) to enhance competition in the pharmaceutical market by stopping anti-competitive agreements between brand name and generic drug or biosimilar manufacturers (and also among generic or biosimilar manufacturers) that limit, delay, or otherwise prevent competition; and (2) to support the purpose and intent of antitrust law by prohibiting anti-competitive practices in the pharmaceutical industry that harm consumers.

Section 3. Unlawful Compensation for Delay. Subsection (a) of Section 3 amends the Federal Trade Commission (FTC) Act by adding a new Section 27 to the FTC Act after Section 26 (15 U.S.C. § 57c–2).

New subsection (a) authorizes the FTC to initiate enforcement proceedings against the parties to an agreement resolving or settling, on a final or interim basis, a patent claim in connection with the sale of a drug product or biological product. In such an action, an agreement shall be presumed to have anti-competitive effects and be in violation of the section if: (1) the agreement provides anything of value to the ANDA or biosimilar biological product application filer; and (2) the agreement includes a limitation on research, development, manufacturing, marketing, or sales of a product for any period of time; unless the parties can demonstrate by clear and convincing evidence that the compensation is solely for other goods or services the filer has promised to provide, or the pro-competitive benefits of the agreement outweigh the anti-competitive effects of the agreement.

New subsection (b) provides that when determining if the parties have met the burden of the exception under subsection (a), the factfinder shall not presume (1) that the entry of a product into the market would not have occurred until the relevant patent or statutory exclusivity expires; or (2) that the agreement for entry of a product prior to the expiration of the relevant patent or statutory exclusivity means that the agreement is pro-competitive.

New subsection (c) provides that nothing in this section shall prohibit a resolution or settlement of a patent infringement claim where the thing of value received by the filer includes only one or more of the following: (1) the right to market and secure final regulatory approval for a product in the U.S. prior to the expiration of any patent that is the basis for the patent infringement claim; or any patent right or other statutory exclusivity that would prevent the marketing of such ANDA product or biosimilar biological product (including certain acceleration clauses that allow for early generic entry and waivers of regulatory and statutory exclusivities that may otherwise block generic entry); (2) any payment for reasonable litigation expenses not to exceed \$7,500,000 in 2019, adjusted each year thereafter to reflect any increases in the Producer Price Index for Legal Services; or (3) a covenant not to sue on any

claim that the ANDA product or biosimilar biological product infringes a United States patent.

New subsection (d) provides that a violation of this section shall be treated as an unfair method of competition under Section 5(a)(1) of the FTC Act. A party has 30 days to file a petition for review of the Commission's decision to a United States Court of Appeals, but the findings of the Commission as to the facts, if supported by evidence, shall be conclusive.

New subsection (e) provides that nothing in this Section shall modify, impair, limit, or supersede the antitrust laws or the right to assert claims under the antitrust laws of any filer of an application to approve a generic drug or a biosimilar product.

New subsection (f) provides for penalties. A civil penalty shall not be greater than three times the value received or given by the parties that is reasonably attributable to violation of this section. The Commission may recover the penalty through a civil action in district court. In such actions, the courts may grant mandatory injunctions and such other and further equitable relief as the courts deem appropriate. If the FTC issues a cease and desist order against a party, the FTC may commence an action under this section at any time before the expiration of one year after such order becomes final. When determining the civil penalty amount, the court shall take into account: (1) the nature, circumstances, gravity, and extent of the violation; (2) the degree of culpability, any history of violations, the ability to pay, any effect on the ability to continue doing business, profits earned by the parties to the agreement, compensation received by the generic or biosimilar biological product application filer; (3) the amount of commerce affected by the violation; and (4) other matters that justice requires.

New subsection (g) sets forth various definitions.

Subsection (b) of Section 3 sets the effective date of the new Section 27. That section applies to all agreements described in section 27(a)(1) entered into on or after the date of enactment of this Act.

Section 4. Notice and Certification of Agreements. Section 4 amends the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 by extending the definition of "Brand Name Drug Company" to include the owners of patents that could be the subject of patent infringement claims arising from the marketing of a biological product in the U.S.; and (2) adding that an official from the company must file a certification regarding the completeness of the materials filed with the Assistant Attorney General and the FTC within 30 days after the filing of any settlement agreement required to be filed under the statute.

Section 5. Notification of Agreements. Section 5 amends the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 by clarifying that the requirement to file certain agreements with the FTC extends to agreements resolving or settling a Patent Trial and Appeal Board proceeding.

Section 6. Forfeiture of 180-Day Exclusivity Period. Section 6 amends the Federal Food, Drug, and Cosmetic Act to eliminate the 180-day exclusivity period for the first-to-file generic drug on the market if the generic drug's manufacturer is found to have violated new section 27 of the Federal Trade Commission Act.

Section 7. Commission Litigation Authority. Section 7 provides the FTC exclusive authority to commence and supervise litigation of any action or appeal under the Act, unless the FTC authorizes the Department of Justice to do so.

Section 8. Report on Additional Exclusion. Section 8 requires the FTC to provide a recommendation to the Committee on the Judiciary of the House of Representatives and the Committee on the Judiciary of the Senate within one year of enactment regarding a potential amendment to add to section 27(c) of the FTC Act an additional exclusion for consideration granted by a branded drug company to a generic drug or biosimilar manufacturer in the form of a release, waiver, or limitation of a claim for damages or other monetary relief.

Section 9. Statute of Limitations. Section 9 requires the FTC to commence an action under new section 27 of the Federal Trade Commission Act, except for an action described in new section 27(f)(2), no later than six years after receiving notice of the settlement agreement under section 1112(d) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

Section 10. Severability. Section 10 provides that if a provision of this Act is held unconstitutional the remainder of this Act will not be affected.

Changes in Existing Law Made by the Bill, as Reported

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, and existing law in which no change is proposed is shown in roman):

FEDERAL TRADE COMMISSION ACT

* * * * *

SEC. 16. (a)(1) Except as otherwise provided in paragraph (2) or (3), if—

(A) before commencing, defending, or intervening in, any civil action involving this Act (including an action to collect a civil penalty) which the Commission, or the Attorney General on behalf of the Commission, is authorized to commence, defend, or intervene in, the Commission gives written notification and undertakes to consult with the Attorney General with respect to such action; and

(B) the Attorney General fails within 45 days after receipt of such notification to commence, defend, or intervene in, such action;

the Commission may commence, defend, or intervene in, and supervise the litigation of, such action and any appeal of such action in its own name by any of its attorneys designated by it for such purpose.

(2) Except as otherwise provided in paragraph (3), in any civil action—

(A) under section 13 of this Act (relating to injunctive relief);

(B) under section 19 of this Act (relating to consumer redress);

(C) to obtain judicial review of a rule prescribed by the Commission, or a cease and desist order issued under section 5 of this Act;

(D) under the second paragraph of section 9 of this Act (relating to enforcement of a subpoena) and under the fourth paragraph of such section (relating to compliance with section 6 of this Act); **[or]**

(E) under section 21A of this Act; *or*

(F) *under section 27;*

the Commission shall have exclusive authority to commence or defend, and supervise the litigation of, such action and any appeal of such action in its own name by any of its attorneys designated by it for such purpose, unless the Commission authorizes the Attorney General to do so. The Commission shall inform the Attorney General of the exercise of such authority and such exercise shall not preclude the Attorney General from intervening on behalf of the United States in such action and any appeal of such action as may be otherwise provided by law.

(3)(A) If the Commission makes a written request to the Attorney General, within the 10-day period which begins on the date of the entry of the judgment in any civil action in which the Commission represented itself pursuant to paragraph (1) or (2), to represent itself through any of its attorneys designated by it for such purpose before the Supreme Court in such action, it may do so, if—

(i) the Attorney General concurs with such request; or

(ii) the Attorney General, within the 60-day period which begins on the date of the entry of such judgment—

(a) refuses to appeal or file a petition for writ of certiorari with respect to such civil action, in which case he shall give written notification to the Commission of the reasons for such refusal within such 60-day period; or

(b) the Attorney General fails to take any action with respect to the Commission's request.

(B) In any case where the Attorney General represents the Commission before the Supreme Court in any civil action in which the Commission represented itself pursuant to paragraph (1) or (2), the Attorney General may not agree to any settlement, compromise, or dismissal of such action, or confess error in the Supreme Court with respect to such action, unless the Commission concurs.

(C) For purposes of this paragraph (with respect to representation before the Supreme Court), the term "Attorney General" includes the Solicitor General.

(4) If, prior to the expiration of the 45-day period specified in paragraph (1) of this section or a 60-day period specified in paragraph (3), any right of the Commission to commence, defend, or intervene in, any such action or appeal may be extinguished due to any procedural requirement of any court with respect to the time in which any pleadings, notice of appeal, or other acts pertaining to such action or appeal may be taken, the Attorney General shall have one-half of the time required to comply with any such procedural requirement of the court (including any extension of such

time granted by the court) for the purpose of commencing, defending, or intervening in the civil action pursuant to paragraph (1) or for the purpose of refusing to appeal or file a petition for writ of certiorari and the written notification or failing to take any action pursuant to paragraph 3(A)(ii).

(5) The provisions of this subsection shall apply notwithstanding chapter 31 of title 28, United States Code, or any other provision of law.

(b) Whenever the Commission has reason to believe that any person, partnership, or corporation is liable for a criminal penalty under this Act, the Commission shall certify the facts to the Attorney General, whose duty it shall be to cause appropriate criminal proceedings to be brought.

(c) FOREIGN LITIGATION.—

(1) COMMISSION ATTORNEYS.—With the concurrence of the Attorney General, the Commission may designate Commission attorneys to assist the Attorney General in connection with litigation in foreign courts on particular matters in which the Commission has an interest.

(2) REIMBURSEMENT FOR FOREIGN COUNSEL.—The Commission is authorized to expend appropriated funds, upon agreement with the Attorney General, to reimburse the Attorney General for the retention of foreign counsel for litigation in foreign courts and for expenses related to litigation in foreign courts in which the Commission has an interest.

(3) LIMITATION ON USE OF FUNDS.—Nothing in this subsection authorizes the payment of claims or judgments from any source other than the permanent and indefinite appropriation authorized by section 1304 of title 31, United States Code.

(4) OTHER AUTHORITY.—The authority provided by this subsection is in addition to any other authority of the Commission or the Attorney General.

* * * * *

SEC. 27. PRESERVING ACCESS TO AFFORDABLE GENERICS AND BIOSIMILARS.

(a) IN GENERAL.—

(1) ENFORCEMENT PROCEEDING.—*The Commission may initiate a proceeding to enforce the provisions of this section against the parties to any agreement resolving or settling, on a final or interim basis, a patent claim, in connection with the sale of a drug product or biological product.*

(2) PRESUMPTION AND VIOLATION.—

(A) IN GENERAL.—*Subject to subparagraph (B), in such a proceeding, an agreement shall be presumed to have anti-competitive effects and shall be a violation of this section if—*

(i) an ANDA filer or a biosimilar biological product application filer receives anything of value, including an exclusive license; and

(ii) the ANDA filer or biosimilar biological product application filer agrees to limit or forgo research, development, manufacturing, marketing, or sales of the

ANDA product or biosimilar biological product, as applicable, for any period of time.

(B) *EXCEPTION.*—Subparagraph (A) shall not apply if the parties to such agreement demonstrate by clear and convincing evidence that—

(i) the value described in subparagraph (A)(i) is compensation solely for other goods or services that the ANDA filer or biosimilar biological product application filer has promised to provide; or

(ii) the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement.

(b) *LIMITATIONS.*—In determining whether the settling parties have met their burden under subsection (a)(2)(B), the fact finder shall not presume—

(1) that entry would not have occurred until the expiration of the relevant patent or statutory exclusivity; or

(2) that the agreement's provision for entry of the ANDA product or biosimilar biological product prior to the expiration of the relevant patent or statutory exclusivity means that the agreement is procompetitive.

(c) *EXCLUSIONS.*—Nothing in this section shall prohibit a resolution or settlement of a patent infringement claim in which the consideration that the ANDA filer or biosimilar biological product application filer receives as part of the resolution or settlement includes only one or more of the following:

(1) The right to market and secure final regulatory approval for the ANDA product or biosimilar biological product at a date, whether certain or contingent, in the United States prior to the expiration of—

(A) any patent that is the basis for the patent infringement claim; or

(B) any patent right or other statutory exclusivity that would prevent the marketing of such ANDA product or biosimilar biological product.

(2) A payment for reasonable litigation expenses not to exceed—

(A) for calendar year 2019, \$7,500,000; and

(B) for calendar year 2020 and each calendar year thereafter, the amount determined for the preceding calendar year adjusted to reflect the percentage increase (if any) in the Producer Price Index for Legal Services published by the Bureau of Labor Statistics of the Department of Labor for the then most recent 12-month period ending December 31.

(3) A covenant not to sue on any claim that the ANDA product or biosimilar biological product infringes a United States patent.

(d) *ENFORCEMENT.*—

(1) *ENFORCEMENT.*—A violation of this section shall be treated as an unfair method of competition under section 5(a)(1) of the Federal Trade Commission Act (15 U.S.C. 45(a)(1)).

(2) *JUDICIAL REVIEW.*—

(A) *IN GENERAL.*—Any party that is subject to a final order of the Commission, issued in an administrative adju-

dicative proceeding under the authority of subsection (a)(1), may, within 30 days of the issuance of such order, petition for review of such order in—

(i) the United States Court of Appeals for the District of Columbia Circuit;

(ii) the United States Court of Appeals for the circuit in which the ultimate parent entity, as defined in section 801.1(a)(3) of title 16, Code of Federal Regulations, or any successor thereto, of the NDA holder or biological product license holder is incorporated as of the date that the NDA or biological product license application, as applicable, is filed with the Commissioner of Food and Drugs; or

(iii) the United States Court of Appeals for the circuit in which the ultimate parent entity of the ANDA filer or biosimilar biological product application filer is incorporated as of the date that the ANDA or biosimilar biological product application is filed with the Commissioner of Food and Drugs.

(B) TREATMENT OF FINDINGS.—*In a proceeding for judicial review of a final order of the Commission, the findings of the Commission as to the facts, if supported by evidence, shall be conclusive.*

(e) ANTITRUST LAWS.—*Nothing in this section shall modify, impair, limit, or supersede the applicability of the antitrust laws as defined in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), and of section 5 of this Act to the extent that section 5 applies to unfair methods of competition. Nothing in this section shall modify, impair, limit, or supersede the right of an ANDA filer or biosimilar biological product application filer to assert claims or counterclaims against any person, under the antitrust laws or other laws relating to unfair competition.*

(f) PENALTIES.—

(1) FORFEITURE.—*Each party that violates or assists in the violation of this section shall forfeit and pay to the United States a civil penalty sufficient to deter violations of this section, but in no event greater than 3 times the value received by the party that is reasonably attributable to the violation of this section. If no such value has been received by the NDA holder, biological product license holder, the ANDA filer, or biosimilar biological product application filer the penalty to the NDA holder, biological product license holder, the ANDA filer, or biosimilar biological product application filer shall be sufficient to deter violations, but in no event greater than 3 times the value given to an ANDA filer or biosimilar biological product application filer reasonably attributable to the violation of this section. Such penalty shall accrue to the United States and may be recovered in a civil action brought by the Commission, in its own name by any of its attorneys designated by it for such purpose, in a district court of the United States against any party that violates this section. In such actions, the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they deem appropriate.*

(2) CEASE AND DESIST.—

(A) *IN GENERAL.*—If the Commission has issued a cease and desist order with respect to a party in an administrative adjudicative proceeding under the authority of subsection (a)(1), an action brought pursuant to paragraph (1) may be commenced against such party at any time before the expiration of 1 year after such order becomes final pursuant to section 5(g).

(B) *EXCEPTION.*—In an action under subparagraph (A), the findings of the Commission as to the material facts in the administrative adjudicative proceeding with respect to the violation of this section by a party shall be conclusive unless—

(i) the terms of such cease and desist order expressly provide that the Commission’s findings shall not be conclusive; or

(ii) the order became final by reason of section 5(g)(1), in which case such finding shall be conclusive if supported by evidence.

(3) *CIVIL PENALTY.*—In determining the amount of the civil penalty described in this section, the court shall take into account—

(A) the nature, circumstances, extent, and gravity of the violation;

(B) with respect to the violator, the degree of culpability, any history of violations, the ability to pay, any effect on the ability to continue doing business, profits earned by the NDA holder, biological product license holder, the ANDA filer, or biosimilar biological product application filer, compensation received by the ANDA filer or biosimilar biological product application filer, and the amount of commerce affected; and

(C) other matters that justice requires.

(4) *REMEDIES IN ADDITION.*—Remedies provided in this subsection are in addition to, and not in lieu of, any other remedy provided by Federal law. Nothing in this paragraph shall be construed to affect any authority of the Commission under any other provision of law.

(g) *DEFINITIONS.*—In this section:

(1) *AGREEMENT.*—The term “agreement” means anything that would constitute an agreement under section 1 of the Sherman Act (15 U.S.C. 1) or section 5 of this Act.

(2) *AGREEMENT RESOLVING OR SETTLING A PATENT INFRINGEMENT CLAIM.*—The term “agreement resolving or settling a patent infringement claim” includes any agreement that is entered into within 30 days of the resolution or the settlement of the claim, or any other agreement that is contingent upon, provides a contingent condition for, or is otherwise related to the resolution or settlement of the claim.

(3) *ANDA.*—The term “ANDA” means an abbreviated new drug application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) or a new drug application filed under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2)).

(4) *ANDA FILER*.—The term “ANDA filer” means a party that owns or controls an ANDA filed with the Food and Drug Administration or has the exclusive rights under such ANDA to distribute the ANDA product.

(5) *ANDA PRODUCT*.—The term “ANDA product” means the product to be manufactured under the ANDA that is the subject of the patent infringement claim.

(6) *BIOLOGICAL PRODUCT*.—The term “biological product” has the meaning given such term in section 351(i)(1) of the Public Health Service Act (42 U.S.C. 262(i)(1)).

(7) *BIOLOGICAL PRODUCT LICENSE APPLICATION*.—The term “biological product license application” means an application under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(8) *BIOLOGICAL PRODUCT LICENSE HOLDER*.—The term “biological product license holder” means—

(A) the holder of an approved biological product license application for a biological product;

(B) a person owning or controlling enforcement of any patents that claim the biological product that is the subject of such approved application; or

(C) the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (A) and (B) (such control to be presumed by direct or indirect share ownership of 50 percent or greater), as well as the licensees, licensors, successors, and assigns of each of the entities.

(9) *BIOSIMILAR BIOLOGICAL PRODUCT*.—The term “biosimilar biological product” means the product to be manufactured under the biosimilar biological product application that is the subject of the patent infringement claim.

(10) *BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION*.—The term “biosimilar biological product application” means an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) for licensure of a biological product as biosimilar to, or interchangeable with, a reference product.

(11) *BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION FILER*.—The term “biosimilar biological product application filer” means a party that owns or controls a biosimilar biological product application filed with the Food and Drug Administration or has the exclusive rights under such application to distribute the biosimilar biological product.

(12) *DRUG PRODUCT*.—The term “drug product” has the meaning given such term in section 314.3(b) of title 21, Code of Federal Regulations (or any successor regulation).

(13) *MARKET*.—The term “market” means the promote, offer for sale, sell, or distribute a drug product.

(14) *NDA*.—The term “NDA” means a new drug application filed under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).

(15) *NDA HOLDER*.—The term “NDA holder” means—

(A) the holder of an approved NDA application for a drug product;

(B) a person owning or controlling enforcement of the patent listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the “FDA Orange Book”) in connection with the NDA; or

(C) the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (A) and (B) (such control to be presumed by direct or indirect share ownership of 50 percent or greater), as well as the licensees, licensors, successors, and assigns of each of the entities.

(16) **PARTY.**—The term “party” means any person, partnership, corporation, or other legal entity.

(17) **PATENT INFRINGEMENT.**—The term “patent infringement” means infringement of any patent or of any filed patent application, including any extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patents of addition, and extensions thereof.

(18) **PATENT INFRINGEMENT CLAIM.**—The term “patent infringement claim” means any allegation made to an ANDA filer or biosimilar biological product application filer, whether or not included in a complaint filed with a court of law, that its ANDA or ANDA product, or biological product license application or biological product, may infringe any patent held by, or exclusively licensed to, the NDA holder or biological product license holder, biological product license holder, the ANDA filer, or biosimilar biological product application filer of the drug product or biological product, as applicable.

(19) **STATUTORY EXCLUSIVITY.**—The term “statutory exclusivity” means those prohibitions on the approval of drug applications under clauses (ii) through (iv) of section 505(c)(3)(E) (5- and 3-year data exclusivity), section 527 (orphan drug exclusivity), or section 505A (pediatric exclusivity) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)(E), 360cc, 355a), or on the licensing of biological product applications under section 351(k)(7) (12-year exclusivity) or paragraph (2) or (3) of section 351(m) (pediatric exclusivity) of the Public Health Service Act (42 U.S.C. 262) or under section 527 of the Federal Food, Drug, and Cosmetic Act (orphan drug exclusivity).

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MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003

* * * * *

TITLE XI—ACCESS TO AFFORDABLE PHARMACEUTICALS

* * * * *

Subtitle B—Federal Trade Commission Review

SEC. 1111. DEFINITIONS.

In this subtitle:

(1) **ANDA.**—The term “ANDA” means an abbreviated drug application, as defined under section 201(aa) of the Federal Food, Drug, and Cosmetic Act.

(2) **ASSISTANT ATTORNEY GENERAL.**—The term “Assistant Attorney General” means the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice.

(3) **BIOSIMILAR BIOLOGICAL PRODUCT.**—The term “biosimilar biological product” means a biological product for which a biosimilar biological product application under section 351(k) of the Public Health Service Act is approved.

(4) **BIOSIMILAR BIOLOGICAL PRODUCT APPLICANT.**—The term “biosimilar biological product applicant” means a person who has filed or received approval for a biosimilar biological product application under section 351(k) of the Public Health Service Act.

(5) **BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION.**—The term “biosimilar biological product application” means an application under section 351(k) of the Public Health Service Act for licensure of a biological product as biosimilar to, or interchangeable with, a reference product.

(6) **BRAND NAME DRUG.**—The term “brand name drug” means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, including an application referred to in section 505(b)(2) of such Act, or a biological product for which an application is approved under section 351(a) of the Public Health Service Act.

(7) **BRAND NAME DRUG COMPANY.**—The term “brand name drug company” means the party that holds the approved application referred to in paragraph (6) for a brand name drug that is a listed drug in an ANDA or a reference product in a biosimilar biological product application, or a party that is the owner of a patent for which information is submitted for such drug under subsection (b) or (c) of section 505 of the Federal Food, Drug, and Cosmetic Act or the owner, or exclusive licensee, of a patent included in a list provided under section 351(l)(3) of the Public Health Service Act *or the owner of a patent for which a claim of infringement could reasonably be asserted against any person for making, using, offering to sell, selling, or importing into the United States a biological product that is the subject of a biosimilar biological product application.*

(8) **COMMISSION.**—The term “Commission” means the Federal Trade Commission.

(9) **GENERIC DRUG.**—The term “generic drug” means a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act is approved.

(10) **GENERIC DRUG APPLICANT.**—The term “generic drug applicant” means a person who has filed or received approval for

an ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act.

(11) LISTED DRUG.—The term “listed drug” means a brand name drug that is listed under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act.

(12) REFERENCE PRODUCT.—The term “reference product” has the meaning given such term in section 351(i) of the Public Health Service Act.

SEC. 1112. NOTIFICATION OF AGREEMENTS.

(a) AGREEMENT WITH BRAND NAME DRUG COMPANY.—

(1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act or a biosimilar biological product applicant who has submitted a biosimilar biological product application and a brand name drug company that enter into an agreement described in paragraph (2) shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of the generic drug that is the subject of the ANDA or the biosimilar biological product that is the subject of the biosimilar biological product application, as applicable.

(2) SUBJECT MATTER OF AGREEMENT.—An agreement described in this paragraph between a generic drug applicant or a biosimilar biological product applicant and a brand name drug company is an agreement regarding—

(A) the manufacture, marketing, or sale of the brand name drug that is the listed drug in the ANDA or the reference product in the biosimilar biological product application involved;

(B) the manufacture, marketing, or sale of the generic drug for which the ANDA was submitted or of the biosimilar biological product for which the biosimilar biological product application was submitted; or

(C) as applicable—

(i) the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act as it applies to such ANDA or to any other ANDA based on the same listed drug; or

(ii) any of the time periods referred to in section 351(k)(6) of the Public Health Service Act as such period applies to such biosimilar biological product application or to any other biosimilar biological product application based on the same reference product.

(b) AGREEMENT WITH ANOTHER GENERIC DRUG APPLICANT OR BIOSIMILAR BIOLOGICAL PRODUCT APPLICANT.—

(1) REQUIREMENT.—

(A) GENERIC DRUGS.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act with respect to a listed drug and another generic drug applicant that has submitted an ANDA containing such a certification for the same listed drug shall each file the agreement in accordance with subsection (c).

The agreement shall be filed prior to the date of the first commercial marketing of either of the generic drugs for which such ANDAs were submitted.

(B) BIOSIMILAR BIOLOGICAL PRODUCTS.—A biosimilar biological product applicant that has submitted a biosimilar biological product application that references a reference product and another biosimilar biological product applicant that has submitted a biosimilar biological product application that references the same reference product shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of either of the biosimilar biological products for which such biosimilar biological product applications were submitted.

(2) SUBJECT MATTER OF AGREEMENT.—An agreement described in this paragraph is, as applicable, an agreement between 2 or more generic drug applicants regarding the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act as it applies to the ANDAs with which the agreement is concerned, an agreement between 2 or more biosimilar biological product applicants regarding a time period referred to in section 351(k)(6) of the Public Health Service Act as it applies to the biosimilar biological product, or an agreement between 2 or more biosimilar biological product applicants regarding the manufacture, marketing, or sale of a biosimilar biological product.

(c) FILING.—

(1) AGREEMENT.—The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and the Commission the text of any such agreement, except that such parties are not required to file an agreement that solely concerns—

- (A) purchase orders for raw material supplies;
- (B) equipment and facility contracts;
- (C) employment or consulting contracts; or
- (D) packaging and labeling contracts.

(2) OTHER AGREEMENTS.—The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and the Commission the text of any agreements between the parties that are not described in such subsections and are contingent upon, provide a contingent condition for, were entered into within 30 days of, or are otherwise related to an agreement that is required in subsection (a) or (b) to be filed in accordance with this subsection.

(3) DESCRIPTION.—In the event that any agreement required in subsection (a) or (b) to be filed in accordance with this subsection has not been reduced to text, each of the parties involved shall file written descriptions of such agreement that are sufficient to disclose all the terms and conditions of the agreement.

(d) CERTIFICATION.—*The Chief Executive Officer or the company official responsible for negotiating any agreement under subsection*

(a) or (b) that is required to be filed under subsection (c), within 30 days after such filing, shall execute and file with the Assistant Attorney General and the Commission a certification as follows: “I declare that the following is true, correct, and complete to the best of my knowledge: The materials filed with the Federal Trade Commission and the Department of Justice under section 1112 of subtitle B of title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, with respect to the agreement referenced in this certification—

“(1) represent the complete, final, and exclusive agreement between the parties;

“(2) include any ancillary agreements that are contingent upon, provide a contingent condition for, or are otherwise related to, the referenced agreement; and

“(3) include written descriptions of any oral agreements, representations, commitments, or promises between the parties that are responsive to subsection (a) or (b) of such section 1112 and have not been reduced to writing.”.

(4) *RULE OF CONSTRUCTION.*—

(A) An agreement that is required in subsection (a) or (b) shall include agreements resolving any outstanding disputes, including agreements resolving or settling a Patent Trial and Appeal Board proceeding.

(B) For purposes of subparagraph (A), the term “Patent Trial and Appeal Board proceeding” means a proceeding conducted by the United States Patent and Trademark Office Patent Trial and Appeal Board, including but not limited to inter parties review, post-grant review, the transitional program for covered business method patents, and derivation proceedings.

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FEDERAL FOOD, DRUG, AND COSMETIC ACT

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CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

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NEW DRUGS

SEC. 505. (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.

(b)(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components

of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug, and (G) any assessments required under section 505B. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture use, or sale of the drug. If a application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences. The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A).

(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)—

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

(3) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(A) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in

the application a statement that the applicant will give notice as required by this paragraph.

(B) TIMING OF NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph—

(i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(C) RECIPIENTS OF NOTICE.—An applicant required under this paragraph to give notice shall give notice to—

(i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(ii) the holder of the approved application under this subsection for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(D) CONTENTS OF NOTICE.—A notice required under this paragraph shall—

(i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(4)(A) An applicant may not amend or supplement an application referred to in paragraph (2) to seek approval of a drug that is a different drug than the drug identified in the application as submitted to the Secretary.

(B) With respect to the drug for which such an application is submitted, nothing in this subsection or subsection (c)(3) prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(5)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or under section 351 of the Public Health Service Act, which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 351 of the Public Health Service Act if the sponsor or applicant

makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size—

(i)(I) of clinical trials intended to form the primary basis of an effectiveness claim; or

(II) in the case where human efficacy studies are not ethical or feasible, of animal and any associated clinical trials which, in combination, are intended to form the primary basis of an effectiveness claim; or

(ii) with respect to an application for approval of a biological product under section 351(k) of the Public Health Service Act, of any necessary clinical study or studies.

The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

(C) Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection or section 351 of the Public Health Service Act (including all scientific and medical matters, chemistry, manufacturing, and controls).

(6) An application submitted under this subsection shall be accompanied by the certification required under section 402(j)(5)(B) of the Public Health Service Act. Such certification shall not be considered an element of such application.

(c)(1) Within one hundred and eighty days after the filing of an application under subsection (b), or such additional period as may

be agreed upon by the Secretary and the applicant, the Secretary shall either—

(A) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

(B) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(2) If the patent information described in subsection (b) could not be filed with the submission of an application under subsection (b) because the application was filed before the patent information was required under subsection (b) or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary, the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b) because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after the date of the enactment of this sentence, and if the holder of an approved application could not file patent information under subsection (b) because no patent had been issued when an application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.

(3) The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined by applying the following to each certification made under subsection (b)(2)(A):

(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) or in both such clauses, the approval may be made effective immediately.

(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A), the approval may be made effective on the date certified under clause (iii).

(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) is received, an action is brought for infringement of the patent that

is the subject of the certification and for which information was submitted to the Secretary under paragraph (2) or subsection (b)(1) before the date on which the application (excluding an amendment or supplement to the application) was submitted. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under subsection (b)(3) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(I) the date on which the court enters judgment reflecting the decision; or

(II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(ii) if before the expiration of such period the district court decides that the patent has been infringed—

(I) if the judgment of the district court is appealed, the approval shall be made effective on—

(aa) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(bb) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(II) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;

(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in clause (i); or

(iv) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in clause (ii).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(D) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

(I) IN GENERAL.—No action may be brought under section 2201 of title 28, United States Code, by an applicant referred to in subsection (b)(2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (C) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) FILING OF CIVIL ACTION.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, United States Code, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant referred to in subsection (b)(2) for the purpose of determining whether an action referred to in subparagraph (C) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a pro-

tective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under subsection (b)(2)(A)(iv) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or this subsection on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(E)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of another application for a drug for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not ob-

tained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b).

(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this clause, no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under subsection (b) after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(A). The approval of such an application shall be made effective in accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after the date of the enactment of this clause and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) if the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(iv) If a supplement to an application approved under subsection (b) is approved after the date of enactment of this clause and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the

person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) if the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this clause, the Secretary may not make the approval of an application submitted under this subsection and for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted and which refers to the drug for which the subsection (b) application was submitted effective before the expiration of two years from the date of enactment of this clause.

(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.

(5)(A) The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect to a qualified indication for a drug, submitted under subsection (b), if such supplemental application complies with subparagraph (B).

(B) A supplemental application is eligible for review as described in subparagraph (A) only if—

(i) there is existing data available and acceptable to the Secretary demonstrating the safety of the drug; and

(ii) all data used to develop the qualified data summaries are submitted to the Secretary as part of the supplemental application.

(C) The Secretary shall post on the Internet website of the Food and Drug Administration and update annually—

(i) the number of applications reviewed solely under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act;

(ii) the average time for completion of review under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act;

(iii) the average time for review of supplemental applications where the Secretary did not use review flexibility under sub-

paragraph (A) or section 351(a)(2)(E) of the Public Health Service Act; and

(iv) the number of applications reviewed under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act for which the Secretary made use of full data sets in addition to the qualified data summary.

(D) In this paragraph—

(i) the term “qualified indication” means an indication for a drug that the Secretary determines to be appropriate for summary level review under this paragraph; and

(ii) the term “qualified data summary” means a summary of clinical data that demonstrates the safety and effectiveness of a drug with respect to a qualified indication.

(d) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b); or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term “substantial evidence” means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness,

the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence. The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process to facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decisionmaking, and the communication of the benefits and risks of new drugs. Nothing in the preceding sentence shall alter the criteria for evaluating an application for marketing approval of a drug.

(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) the patent information prescribed by subsection (c) was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or (5) that the application contains any untrue statement of a material fact: *Provided*, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application submitted under subsection (b) or (j) with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (k) or to comply with the notice requirements of section 510(k)(2), or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength,

quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based. The Secretary may withdraw the approval of an application submitted under this section, or suspend the approval of such an application, as provided under this subsection, without first ordering the applicant to submit an assessment of the approved risk evaluation and mitigation strategy for the drug under section 505-1(g)(2)(D).

(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

(g) Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the Department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

(h) An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evi-

dence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i)(1) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon—

(A) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, or pre-clinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

(B) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings;

(C) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b); and

(D) the submission to the Secretary by the manufacturer or the sponsor of the investigation of a new drug of a statement of intent regarding whether the manufacturer or sponsor has plans for assessing pediatric safety and efficacy.

(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including—

(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies.

(3)(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a “clinical hold”) if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that—

(i) the drug involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before the date of the enactment of the Food and Drug Administration Modernization Act of 1997).

(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

(4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible, it is contrary to the best interests of such human beings, or the proposed clinical testing poses no more than minimal risk to such human beings and includes appropriate safeguards as prescribed to protect the rights, safety, and welfare of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs. The Secretary shall update such regulations to require inclusion in the informed consent documents and process a statement that clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to subsection (j) of section 402 of the Public Health Service Act.

(j)(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the

new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 201(p), and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1);

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)—

(I) that such patent information has not been filed,

- (II) that such patent has expired,
- (III) of the date on which such patent will expire, or
- (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and
- (viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(i) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) TIMING OF NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) RECIPIENTS OF NOTICE.—An applicant required under this subparagraph to give notice shall give notice to—

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) CONTENTS OF NOTICE.—A notice required under this subparagraph shall—

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds—

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(D)(i) An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(iii) Within 60 days after the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Secretary shall issue guidance defining the term “listed drug” for purposes of this subparagraph.

(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant;

or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a sub-

stantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 201(p),

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in

the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e), the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) for grounds described in the first sentence of subsection (e), the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) 180-DAY EXCLUSIVITY PERIOD.—

(I) EFFECTIVENESS OF APPLICATION.—Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) DEFINITIONS.—In this paragraph:

(aa) 180-DAY EXCLUSIVITY PERIOD.—The term “180-day exclusivity period” means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) FIRST APPLICANT.—As used in this subsection, the term “first applicant” means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) SUBSTANTIALLY COMPLETE APPLICATION.—As used in this subsection, the term “substantially complete application” means an application under this subsection that on its face is sufficiently complete to

permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) TENTATIVE APPROVAL.—

(AA) IN GENERAL.—The term “tentative approval” means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 505A, or there is a 7-year period of exclusivity for the listed drug under section 527.

(BB) LIMITATION.—A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(v) 180-DAY EXCLUSIVITY PERIOD FOR COMPETITIVE GENERIC THERAPIES.—

(I) EFFECTIVENESS OF APPLICATION.—Subject to subparagraph (D)(iv), if the application is for a drug that is the same as a competitive generic therapy for which any first approved applicant has commenced commercial marketing, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the competitive generic therapy (including the commercial marketing of the listed drug) by any first approved applicant.

(II) LIMITATION.—The exclusivity period under subclause (I) shall not apply with respect to a competitive generic therapy that has previously received an exclusivity period under subclause (I).

(III) DEFINITIONS.—In this clause and subparagraph (D)(iv):

(aa) The term “competitive generic therapy” means a drug—

(AA) that is designated as a competitive generic therapy under section 506H; and

(BB) for which there are no unexpired patents or exclusivities on the list of products described in section 505(j)(7)(A) at the time of submission.

(bb) The term “first approved applicant” means any applicant that has submitted an application that—

(AA) is for a competitive generic therapy that is approved on the first day on which any application for such competitive generic therapy is approved;

(BB) is not eligible for a 180-day exclusivity period under clause (iv) for the drug that is the subject of the application for the competitive generic therapy; and

(CC) is not for a drug for which all drug versions have forfeited eligibility for a 180-day ex-

clusivity period under clause (iv) pursuant to subparagraph (D).

(C) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

(I) IN GENERAL.—No action may be brought under section 2201 of title 28, United States Code, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) FILING OF CIVIL ACTION.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, United States Code, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been

entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—

(i) DEFINITION OF FORFEITURE EVENT.—In this subparagraph, the term “forfeiture event”, with respect to an application under this subsection, means the occurrence of any of the following:

(I) FAILURE TO MARKET.—The first applicant fails to market the drug by the later of—

(aa) the earlier of the date that is—

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) is withdrawn by the holder of the application approved under subsection (b).

(II) WITHDRAWAL OF APPLICATION.—The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) AMENDMENT OF CERTIFICATION.—The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) AGREEMENT WITH ANOTHER APPLICANT, THE LISTED DRUG APPLICATION HOLDER, OR A PATENT OWNER.—The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certifi-

cation under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated *section 27 of the Federal Trade Commission Act* or the antitrust laws (as defined in section 1 of the Clayton Act (15 U.S.C. 12), except that the term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that that section applies to unfair methods of competition).

(VI) EXPIRATION OF ALL PATENTS.—All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) FORFEITURE.—The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) SUBSEQUENT APPLICANT.—If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(iv) SPECIAL FORFEITURE RULE FOR COMPETITIVE GENERIC THERAPY.—The 180-day exclusivity period described in subparagraph (B)(v) shall be forfeited by a first approved applicant if the applicant fails to market the competitive generic therapy within 75 days after the date on which the approval of the first approved applicant's application for the competitive generic therapy is made effective.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(F)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted

under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b).

(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this subsection, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after the date of enactment of this subsection and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) for such drug.

(iv) If a supplement to an application approved under subsection (b) is approved after the date of enactment of this subsection and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) appli-

cation was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from the date of enactment of this subsection.

(6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under subsection (e) or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(7)(A)(i) Within sixty days of the date of the enactment of this subsection, the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) before the date of the enactment of this subsection;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or the date of enactment, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (e) or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending

on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(8) For purposes of this subsection:

(A)(i) The term “bioavailability” means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

(10)(A) If the proposed labeling of a drug that is the subject of an application under this subsection differs from the listed drug due to a labeling revision described under clause (i), the drug that is the subject of such application shall, notwithstanding any other

provision of this Act, be eligible for approval and shall not be considered misbranded under section 502 if—

(i) the application is otherwise eligible for approval under this subsection but for expiration of patent, an exclusivity period, or of a delay in approval described in paragraph (5)(B)(iii), and a revision to the labeling of the listed drug has been approved by the Secretary within 60 days of such expiration;

(ii) the labeling revision described under clause (i) does not include a change to the “Warnings” section of the labeling;

(iii) the sponsor of the application under this subsection agrees to submit revised labeling of the drug that is the subject of such application not later than 60 days after the notification of any changes to such labeling required by the Secretary; and

(iv) such application otherwise meets the applicable requirements for approval under this subsection.

(B) If, after a labeling revision described in subparagraph (A)(i), the Secretary determines that the continued presence in interstate commerce of the labeling of the listed drug (as in effect before the revision described in subparagraph (A)(i)) adversely impacts the safe use of the drug, no application under this subsection shall be eligible for approval with such labeling.

(11)(A) Subject to subparagraph (B), the Secretary shall prioritize the review of, and act within 8 months of the date of the submission of, an original abbreviated new drug application submitted for review under this subsection that is for a drug—

(i) for which there are not more than 3 approved drug products listed under paragraph (7) and for which there are no blocking patents and exclusivities; or

(ii) that has been included on the list under section 506E.

(B) To qualify for priority review under this paragraph, not later than 60 days prior to the submission of an application described in subparagraph (A) or that the Secretary may prioritize pursuant to subparagraph (D), the applicant shall provide complete, accurate information regarding facilities involved in manufacturing processes and testing of the drug that is the subject of the application, including facilities in corresponding Type II active pharmaceutical ingredients drug master files referenced in an application and sites or organizations involved in bioequivalence and clinical studies used to support the application, to enable the Secretary to make a determination regarding whether an inspection of a facility is necessary. Such information shall include the relevant (as determined by the Secretary) sections of such application, which shall be unchanged relative to the date of the submission of such application, except to the extent that a change is made to such information to exclude a facility that was not used to generate data to meet any application requirements for such submission and that is not the only facility intended to conduct one or more unit operations in commercial production. Information provided by an applicant under this subparagraph shall not be considered the submission of an application under this subsection.

(C) The Secretary may expedite an inspection or reinspection under section 704 of an establishment that proposes to manufacture a drug described in subparagraph (A).

(D) Nothing in this paragraph shall prevent the Secretary from prioritizing the review of other applications as the Secretary determines appropriate.

(12) The Secretary shall publish on the internet website of the Food and Drug Administration, and update at least once every 6 months, a list of all drugs approved under subsection (c) for which all patents and periods of exclusivity under this Act have expired and for which no application has been approved under this subsection.

(13) Upon the request of an applicant regarding one or more specified pending applications under this subsection, the Secretary shall, as appropriate, provide review status updates indicating the categorical status of the applications by each relevant review discipline.

(k)(1) In the case of any drug for which an approval of an application filed under subsection (b) or (j) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section. Regulations and orders issued under this subsection and under subsection (i) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(3) ACTIVE POSTMARKET RISK IDENTIFICATION.—

(A) DEFINITION.—In this paragraph, the term “data” refers to information with respect to a drug approved under this section or under section 351 of the Public Health Service Act, including claims data, patient survey data, standardized analytic files that allow for the pooling and analysis of data from disparate data environments, and any other data deemed appropriate by the Secretary.

(B) DEVELOPMENT OF POSTMARKET RISK IDENTIFICATION AND ANALYSIS METHODS.—The Secretary shall, not later than 2 years after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, in collaboration with public, academic, and private entities—

(i) develop methods to obtain access to disparate data sources including the data sources specified in subparagraph (C);

(ii) develop validated methods for the establishment of a postmarket risk identification and analysis system

to link and analyze safety data from multiple sources, with the goals of including, in aggregate—

- (I) at least 25,000,000 patients by July 1, 2010; and
- (II) at least 100,000,000 patients by July 1, 2012; and
- (iii) convene a committee of experts, including individuals who are recognized in the field of protecting data privacy and security, to make recommendations to the Secretary on the development of tools and methods for the ethical and scientific uses for, and communication of, postmarketing data specified under subparagraph (C), including recommendations on the development of effective research methods for the study of drug safety questions.

(C) ESTABLISHMENT OF THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—

(i) IN GENERAL.—The Secretary shall, not later than 1 year after the development of the risk identification and analysis methods under subparagraph (B), establish and maintain procedures—

(I) for risk identification and analysis based on electronic health data, in compliance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and in a manner that does not disclose individually identifiable health information in violation of paragraph (4)(B);

(II) for the reporting (in a standardized form) of data on all serious adverse drug experiences (as defined in section 505–1(b)) submitted to the Secretary under paragraph (1), and those adverse events submitted by patients, providers, and drug sponsors, when appropriate;

(III) to provide for active adverse event surveillance using the following data sources, as available:

(aa) Federal health-related electronic data (such as data from the Medicare program and the health systems of the Department of Veterans Affairs);

(bb) private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data); and

(cc) other data as the Secretary deems necessary to create a robust system to identify adverse events and potential drug safety signals;

(IV) to identify certain trends and patterns with respect to data accessed by the system;

(V) to provide regular reports to the Secretary concerning adverse event trends, adverse event patterns, incidence and prevalence of adverse events, and other information the Secretary deter-

mines appropriate, which may include data on comparative national adverse event trends; and

(VI) to enable the program to export data in a form appropriate for further aggregation, statistical analysis, and reporting.

(ii) **TIMELINESS OF REPORTING.**—The procedures established under clause (i) shall ensure that such data are accessed, analyzed, and reported in a timely, routine, and systematic manner, taking into consideration the need for data completeness, coding, cleansing, and standardized analysis and transmission.

(iii) **PRIVATE SECTOR RESOURCES.**—To ensure the establishment of the active postmarket risk identification and analysis system under this subsection not later than 1 year after the development of the risk identification and analysis methods under subparagraph (B), as required under clause (i), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

(iv) **COMPLEMENTARY APPROACHES.**—To the extent the active postmarket risk identification and analysis system under this subsection is not sufficient to gather data and information relevant to a priority drug safety question, the Secretary shall develop, support, and participate in complementary approaches to gather and analyze such data and information, including—

(I) approaches that are complementary with respect to assessing the safety of use of a drug in domestic populations not included, or underrepresented, in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children); and

(II) existing approaches such as the Vaccine Adverse Event Reporting System and the Vaccine Safety Datalink or successor databases.

(v) **AUTHORITY FOR CONTRACTS.**—The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subparagraph.

(4) **ADVANCED ANALYSIS OF DRUG SAFETY DATA.**—

(A) **PURPOSE.**—The Secretary shall establish collaborations with public, academic, and private entities, which may include the Centers for Education and Research on Therapeutics under section 912 of the Public Health Service Act, to provide for advanced analysis of drug safety data described in paragraph (3)(C) and other information that is publicly available or is provided by the Secretary, in order to—

(i) improve the quality and efficiency of postmarket drug safety risk-benefit analysis;

(ii) provide the Secretary with routine access to outside expertise to study advanced drug safety questions; and

(iii) enhance the ability of the Secretary to make timely assessments based on drug safety data.

(B) PRIVACY.—Such analysis shall not disclose individually identifiable health information when presenting such drug safety signals and trends or when responding to inquiries regarding such drug safety signals and trends.

(C) PUBLIC PROCESS FOR PRIORITY QUESTIONS.—At least biannually, the Secretary shall seek recommendations from the Drug Safety and Risk Management Advisory Committee (or any successor committee) and from other advisory committees, as appropriate, to the Food and Drug Administration on—

- (i) priority drug safety questions; and
- (ii) mechanisms for answering such questions, including through—

- (I) active risk identification under paragraph (3); and

- (II) when such risk identification is not sufficient, postapproval studies and clinical trials under subsection (o)(3).

(D) PROCEDURES FOR THE DEVELOPMENT OF DRUG SAFETY COLLABORATIONS.—

(i) IN GENERAL.—Not later than 180 days after the date of the establishment of the active postmarket risk identification and analysis system under this subsection, the Secretary shall establish and implement procedures under which the Secretary may routinely contract with one or more qualified entities to—

- (I) classify, analyze, or aggregate data described in paragraph (3)(C) and information that is publicly available or is provided by the Secretary;

- (II) allow for prompt investigation of priority drug safety questions, including—

- (aa) unresolved safety questions for drugs or classes of drugs; and

- (bb) for a newly-approved drugs, safety signals from clinical trials used to approve the drug and other preapproval trials; rare, serious drug side effects; and the safety of use in domestic populations not included, or underrepresented, in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children);

- (III) perform advanced research and analysis on identified drug safety risks;

- (IV) focus postapproval studies and clinical trials under subsection (o)(3) more effectively on cases for which reports under paragraph (1) and other safety signal detection is not sufficient to resolve whether there is an elevated risk of a serious adverse event associated with the use of a drug; and

- (V) carry out other activities as the Secretary deems necessary to carry out the purposes of this paragraph.

(ii) REQUEST FOR SPECIFIC METHODOLOGY.—The procedures described in clause (i) shall permit the Secretary to request that a specific methodology be used by the qualified entity. The qualified entity shall work with the Secretary to finalize the methodology to be used.

(E) USE OF ANALYSES.—The Secretary shall provide the analyses described in this paragraph, including the methods and results of such analyses, about a drug to the sponsor or sponsors of such drug.

(F) QUALIFIED ENTITIES.—

(i) IN GENERAL.—The Secretary shall enter into contracts with a sufficient number of qualified entities to develop and provide information to the Secretary in a timely manner.

(ii) QUALIFICATION.—The Secretary shall enter into a contract with an entity under clause (i) only if the Secretary determines that the entity has a significant presence in the United States and has one or more of the following qualifications:

(I) The research, statistical, epidemiologic, or clinical capability and expertise to conduct and complete the activities under this paragraph, including the capability and expertise to provide the Secretary de-identified data consistent with the requirements of this subsection.

(II) An information technology infrastructure in place to support electronic data and operational standards to provide security for such data.

(III) Experience with, and expertise on, the development of drug safety and effectiveness research using electronic population data.

(IV) An understanding of drug development or risk/benefit balancing in a clinical setting.

(V) Other expertise which the Secretary deems necessary to fulfill the activities under this paragraph.

(G) CONTRACT REQUIREMENTS.—Each contract with a qualified entity under subparagraph (F)(i) shall contain the following requirements:

(i) ENSURING PRIVACY.—The qualified entity shall ensure that the entity will not use data under this subsection in a manner that—

(I) violates the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996;

(II) violates sections 552 or 552a of title 5, United States Code, with regard to the privacy of individually-identifiable beneficiary health information; or

(III) discloses individually identifiable health information when presenting drug safety signals and trends or when responding to inquiries regarding drug safety signals and trends.

Nothing in this clause prohibits lawful disclosure for other purposes.

(ii) COMPONENT OF ANOTHER ORGANIZATION.—If a qualified entity is a component of another organization—

(I) the qualified entity shall establish appropriate security measures to maintain the confidentiality and privacy of such data; and

(II) the entity shall not make an unauthorized disclosure of such data to the other components of the organization in breach of such confidentiality and privacy requirement.

(iii) TERMINATION OR NONRENEWAL.—If a contract with a qualified entity under this subparagraph is terminated or not renewed, the following requirements shall apply:

(I) CONFIDENTIALITY AND PRIVACY PROTECTIONS.—The entity shall continue to comply with the confidentiality and privacy requirements under this paragraph with respect to all data disclosed to the entity.

(II) DISPOSITION OF DATA.—The entity shall return any data disclosed to such entity under this subsection to which it would not otherwise have access or, if returning the data is not practicable, destroy the data.

(H) COMPETITIVE PROCEDURES.—The Secretary shall use competitive procedures (as defined in section 4(5) of the Federal Procurement Policy Act) to enter into contracts under subparagraph (G).

(I) REVIEW OF CONTRACT IN THE EVENT OF A MERGER OR ACQUISITION.—The Secretary shall review the contract with a qualified entity under this paragraph in the event of a merger or acquisition of the entity in order to ensure that the requirements under this paragraph will continue to be met.

(J) COORDINATION.—In carrying out this paragraph, the Secretary shall provide for appropriate communications to the public, scientific, public health, and medical communities, and other key stakeholders, and to the extent practicable shall coordinate with the activities of private entities, professional associations, or other entities that may have sources of drug safety data.

(5) The Secretary shall—

(A) conduct regular screenings of the Adverse Event Reporting System database and post a quarterly report on the Adverse Event Reporting System Web site of any new safety information or potential signal of a serious risk identified by Adverse Event Reporting System within the last quarter; and

(B) on an annual basis, review the entire backlog of postmarket safety commitments to determine which commitments require revision or should be eliminated, report to the Congress on these determinations, and assign start

- dates and estimated completion dates for such commitments; and
- (C) make available on the Internet website of the Food and Drug Administration—
- (i) guidelines, developed with input from experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that detail best practices for drug safety surveillance using the Adverse Event Reporting System; and
 - (ii) criteria for public posting of adverse event signals.
- (1)(1) Safety and effectiveness data and information which has been submitted in an application under subsection (b) for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—
- (A) if no work is being or will be undertaken to have the application approved,
 - (B) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,
 - (C) if approval of the application under subsection (c) is withdrawn and all legal appeals have been exhausted,
 - (D) if the Secretary has determined that such drug is not a new drug, or
 - (E) upon the effective date of the approval of the first application under subsection (j) which refers to such drug or upon the date upon which the approval of an application under subsection (j) which refers to such drug could be made effective if such an application had been submitted.
- (2) ACTION PACKAGE FOR APPROVAL.—
- (A) ACTION PACKAGE.—The Secretary shall publish the action package for approval of an application under subsection (b) or section 351 of the Public Health Service Act on the Internet Web site of the Food and Drug Administration—
- (i) not later than 30 days after the date of approval of such application for a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 351 of the Public Health Service Act; and
 - (ii) not later than 30 days after the third request for such action package for approval received under section 552 of title 5, United States Code, for any other drug.
- (B) IMMEDIATE PUBLICATION OF SUMMARY REVIEW.—Notwithstanding subparagraph (A), the Secretary shall publish, on the Internet Web site of the Food and Drug Administration, the materials described in subparagraph (C)(iv) not later than 48 hours after the date of approval of the drug, except where such materials require redaction by the Secretary.
- (C) CONTENTS.—An action package for approval of an application under subparagraph (A) shall be dated and shall include the following:
- (i) Documents generated by the Food and Drug Administration related to review of the application.
 - (ii) Documents pertaining to the format and content of the application generated during drug development.

(iii) Labeling submitted by the applicant.

(iv) A summary review that documents conclusions from all reviewing disciplines about the drug, noting any critical issues and disagreements with the applicant and within the review team and how they were resolved, recommendations for action, and an explanation of any nonconcurrency with review conclusions.

(v) The Division Director and Office Director's decision document which includes—

(I) a brief statement of concurrence with the summary review;

(II) a separate review or addendum to the review if disagreeing with the summary review; and

(III) a separate review or addendum to the review to add further analysis.

(vi) Identification by name of each officer or employee of the Food and Drug Administration who—

(I) participated in the decision to approve the application; and

(II) consents to have his or her name included in the package.

(D) REVIEW.—A scientific review of an application is considered the work of the reviewer and shall not be altered by management or the reviewer once final.

(E) CONFIDENTIAL INFORMATION.—This paragraph does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter listed in section 552(b) of title 5, United States Code.

(m) For purposes of this section, the term “patent” means a patent issued by the United States Patent and Trademark Office.

(n)(1) For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under section 505 or section 351 of the Public Health Service Act, the Secretary shall establish panels of experts or use panels of experts established before the date of enactment of the Food and Drug Administration Modernization Act of 1997, or both.

(2) The Secretary may delegate the appointment and oversight authority granted under section 1004 to a director of a center or successor entity within the Food and Drug Administration.

(3) The Secretary shall make appointments to each panel established under paragraph (1) so that each panel shall consist of—

(A) members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the development, manufacture, or utilization of such drugs;

(B) members with diverse expertise in such fields as clinical and administrative medicine, pharmacy, pharmacology, pharmacoeconomics, biological and physical sciences, and other related professions;

(C) a representative of consumer interests, and a representative of interests of the drug manufacturing industry not di-

rectly affected by the matter to be brought before the panel; and

(D) two or more members who are specialists or have other expertise in the particular disease or condition for which the drug under review is proposed to be indicated.

Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this Act may be a voting member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

(4) The Secretary shall, as appropriate, provide education and training to each new panel member before such member participates in a panel's activities, including education regarding requirements under this Act and related regulations of the Secretary, and the administrative processes and procedures related to panel meetings.

(5) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation for each day so engaged, including traveltime, at rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above grade GS-15 of the General Schedule. While serving away from their homes or regular places of business, panel members may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

(6) The Secretary shall ensure that scientific advisory panels meet regularly and at appropriate intervals so that any matter to be reviewed by such a panel can be presented to the panel not more than 60 days after the matter is ready for such review. Meetings of the panel may be held using electronic communication to convene the meetings.

(7) Within 90 days after a scientific advisory panel makes recommendations on any matter under its review, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommendations of the panel, and notify the affected persons of the final decision on the matter, or of the reasons that no such decision has been reached. Each such final decision shall be documented including the rationale for the decision.

(o) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING.—

(1) IN GENERAL.—A responsible person may not introduce or deliver for introduction into interstate commerce the new drug involved if the person is in violation of a requirement established under paragraph (3) or (4) with respect to the drug.

(2) DEFINITIONS.—For purposes of this subsection:

(A) RESPONSIBLE PERSON.—The term “responsible person” means a person who—

(i) has submitted to the Secretary a covered application that is pending; or

(ii) is the holder of an approved covered application.

(B) COVERED APPLICATION.—The term “covered application” means—

(i) an application under subsection (b) for a drug that is subject to section 503(b); and

(ii) an application under section 351 of the Public Health Service Act.

(C) NEW SAFETY INFORMATION; SERIOUS RISK.—The terms “new safety information”, “serious risk”, and “signal of a serious risk” have the meanings given such terms in section 505–1(b).

(3) STUDIES AND CLINICAL TRIALS.—

(A) IN GENERAL.—For any or all of the purposes specified in subparagraph (B), the Secretary may, subject to subparagraph (D), require a responsible person for a drug to conduct a postapproval study or studies of the drug, or a postapproval clinical trial or trials of the drug, on the basis of scientific data deemed appropriate by the Secretary, including information regarding chemically-related or pharmacologically-related drugs.

(B) PURPOSES OF STUDY OR CLINICAL TRIAL.—The purposes referred to in this subparagraph with respect to a postapproval study or postapproval clinical trial are the following:

(i) To assess a known serious risk related to the use of the drug involved.

(ii) To assess signals of serious risk related to the use of the drug.

(iii) To identify an unexpected serious risk when available data indicates the potential for a serious risk.

(C) ESTABLISHMENT OF REQUIREMENT AFTER APPROVAL OF COVERED APPLICATION.—The Secretary may require a postapproval study or studies or postapproval clinical trial or trials for a drug for which an approved covered application is in effect as of the date on which the Secretary seeks to establish such requirement only if the Secretary becomes aware of new safety information.

(D) DETERMINATION BY SECRETARY.—

(i) POSTAPPROVAL STUDIES.—The Secretary may not require the responsible person to conduct a study under this paragraph, unless the Secretary makes a determination that the reports under subsection (k)(1) and the active postmarket risk identification and analysis system as available under subsection (k)(3) will not be sufficient to meet the purposes set forth in subparagraph (B).

(ii) POSTAPPROVAL CLINICAL TRIALS.—The Secretary may not require the responsible person to conduct a clinical trial under this paragraph, unless the Secretary makes a determination that a postapproval study or studies will not be sufficient to meet the purposes set forth in subparagraph (B).

(E) NOTIFICATION; TIMETABLES; PERIODIC REPORTS.—

(i) NOTIFICATION.—The Secretary shall notify the responsible person regarding a requirement under this paragraph to conduct a postapproval study or clinical

trial by the target dates for communication of feedback from the review team to the responsible person regarding proposed labeling and postmarketing study commitments as set forth in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007.

(ii) TIMETABLE; PERIODIC REPORTS.—For each study or clinical trial required to be conducted under this paragraph, the Secretary shall require that the responsible person submit a timetable for completion of the study or clinical trial. With respect to each study required to be conducted under this paragraph or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on the status of such study including whether any difficulties in completing the study have been encountered. With respect to each clinical trial required to be conducted under this paragraph or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on the status of such clinical trial including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to the requirements under section 402(j) of the Public Health Service Act. If the responsible person fails to comply with such timetable or violates any other requirement of this subparagraph, the responsible person shall be considered in violation of this subsection, unless the responsible person demonstrates good cause for such noncompliance or such other violation. The Secretary shall determine what constitutes good cause under the preceding sentence.

(F) DISPUTE RESOLUTION.—The responsible person may appeal a requirement to conduct a study or clinical trial under this paragraph using dispute resolution procedures established by the Secretary in regulation and guidance.

(4) SAFETY LABELING CHANGES REQUESTED BY SECRETARY.—

(A) NEW SAFETY OR NEW EFFECTIVENESS INFORMATION.—

If the Secretary becomes aware of new information, including any new safety information or information related to reduced effectiveness, that the Secretary determines should be included in the labeling of the drug, the Secretary shall promptly notify the responsible person or, if the same drug approved under section 505(b) is not currently marketed, the holder of an approved application under 505(j).

(B) RESPONSE TO NOTIFICATION.—Following notification pursuant to subparagraph (A), the responsible person or the holder of the approved application under section 505(j) shall within 30 days—

(i) submit a supplement proposing changes to the approved labeling to reflect the new safety information, including changes to boxed warnings, contraindications, warnings, precautions, or adverse reactions, or new effectiveness information; or

(ii) notify the Secretary that the responsible person or the holder of the approved application under section 505(j) does not believe a labeling change is warranted and submit a statement detailing the reasons why such a change is not warranted.

(C) REVIEW.—Upon receipt of such supplement, the Secretary shall promptly review and act upon such supplement. If the Secretary disagrees with the proposed changes in the supplement or with the statement setting forth the reasons why no labeling change is necessary, the Secretary shall initiate discussions to reach agreement on whether the labeling for the drug should be modified to reflect the new safety or new effectiveness information, and if so, the contents of such labeling changes.

(D) DISCUSSIONS.—Such discussions shall not extend for more than 30 days after the response to the notification under subparagraph (B), unless the Secretary determines an extension of such discussion period is warranted.

(E) ORDER.—Within 15 days of the conclusion of the discussions under subparagraph (D), the Secretary may issue an order directing the responsible person or the holder of the approved application under section 505(j) to make such a labeling change as the Secretary deems appropriate to address the new safety or new effectiveness information. Within 15 days of such an order, the responsible person or the holder of the approved application under section 505(j) shall submit a supplement containing the labeling change.

(F) DISPUTE RESOLUTION.—Within 5 days of receiving an order under subparagraph (E), the responsible person or the holder of the approved application under section 505(j) may appeal using dispute resolution procedures established by the Secretary in regulation and guidance.

(G) VIOLATION.—If the responsible person or the holder of the approved application under section 505(j) has not submitted a supplement within 15 days of the date of such order under subparagraph (E), and there is no appeal or dispute resolution proceeding pending, the responsible person or holder shall be considered to be in violation of this subsection. If at the conclusion of any dispute resolution procedures the Secretary determines that a supplement must be submitted and such a supplement is not submitted within 15 days of the date of that determination, the responsible person or holder shall be in violation of this subsection.

(H) PUBLIC HEALTH THREAT.—Notwithstanding subparagraphs (A) through (F), if the Secretary concludes that such a labeling change is necessary to protect the public health, the Secretary may accelerate the timelines in such subparagraphs.

(I) RULE OF CONSTRUCTION.—This paragraph shall not be construed to affect the responsibility of the responsible person or the holder of the approved application under section 505(j) to maintain its label in accordance with existing requirements, including subpart B of part 201 and sections 314.70 and 601.12 of title 21, Code of Federal Regulations (or any successor regulations).

(5) NON-DELEGATION.—Determinations by the Secretary under this subsection for a drug shall be made by individuals at or above the level of individuals empowered to approve a drug (such as division directors within the Center for Drug Evaluation and Research).

(p) RISK EVALUATION AND MITIGATION STRATEGY.—

(1) IN GENERAL.—A person may not introduce or deliver for introduction into interstate commerce a new drug if—

(A)(i) the application for such drug is approved under subsection (b) or (j) and is subject to section 503(b); or

(ii) the application for such drug is approved under section 351 of the Public Health Service Act; and

(B) a risk evaluation and mitigation strategy is required under section 505–1 with respect to the drug and the person fails to maintain compliance with the requirements of the approved strategy or with other requirements under section 505–1, including requirements regarding assessments of approved strategies.

(2) CERTAIN POSTMARKET STUDIES.—The failure to conduct a postmarket study under section 506, subpart H of part 314, or subpart E of part 601 of title 21, Code of Federal Regulations (or any successor regulations), is deemed to be a violation of paragraph (1).

(q) PETITIONS AND CIVIL ACTIONS REGARDING APPROVAL OF CERTAIN APPLICATIONS.—

(1) IN GENERAL.—

(A) DETERMINATION.—The Secretary shall not delay approval of a pending application submitted under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act because of any request to take any form of action relating to the application, either before or during consideration of the request, unless—

(i) the request is in writing and is a petition submitted to the Secretary pursuant to section 10.30 or 10.35 of title 21, Code of Federal Regulations (or any successor regulations); and

(ii) the Secretary determines, upon reviewing the petition, that a delay is necessary to protect the public health.

Consideration of the petition shall be separate and apart from review and approval of any application.

(B) NOTIFICATION.—If the Secretary determines under subparagraph (A) that a delay is necessary with respect to an application, the Secretary shall provide to the applicant, not later than 30 days after making such determination, the following information:

(i) Notification of the fact that a determination under subparagraph (A) has been made.

(ii) If applicable, any clarification or additional data that the applicant should submit to the docket on the petition to allow the Secretary to review the petition promptly.

(iii) A brief summary of the specific substantive issues raised in the petition which form the basis of the determination.

(C) **FORMAT.**—The information described in subparagraph (B) shall be conveyed via either, at the discretion of the Secretary—

(i) a document; or

(ii) a meeting with the applicant involved.

(D) **PUBLIC DISCLOSURE.**—Any information conveyed by the Secretary under subparagraph (C) shall be considered part of the application and shall be subject to the disclosure requirements applicable to information in such application.

(E) **DENIAL BASED ON INTENT TO DELAY.**—If the Secretary determines that a petition or a supplement to the petition was submitted with the primary purpose of delaying the approval of an application and the petition does not on its face raise valid scientific or regulatory issues, the Secretary may deny the petition at any point based on such determination. The Secretary may issue guidance to describe the factors that will be used to determine under this subparagraph whether a petition is submitted with the primary purpose of delaying the approval of an application.

(F) **FINAL AGENCY ACTION.**—The Secretary shall take final agency action on a petition not later than 150 days after the date on which the petition is submitted. The Secretary shall not extend such period for any reason, including—

(i) any determination made under subparagraph (A);

(ii) the submission of comments relating to the petition or supplemental information supplied by the petitioner; or

(iii) the consent of the petitioner.

(G) **EXTENSION OF 30-MONTH PERIOD.**—If the filing of an application resulted in first-applicant status under subsection (j)(5)(D)(i)(IV) and approval of the application was delayed because of a petition, the 30-month period under such subsection is deemed to be extended by a period of time equal to the period beginning on the date on which the Secretary received the petition and ending on the date of final agency action on the petition (inclusive of such beginning and ending dates), without regard to whether the Secretary grants, in whole or in part, or denies, in whole or in part, the petition.

(H) **CERTIFICATION.**—The Secretary shall not consider a petition for review unless the party submitting such petition does so in written form and the subject document is

signed and contains the following certification: "I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: _____. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.", with the date on which such information first became known to such party and the names of such persons or organizations inserted in the first and second blank space, respectively.

(I) VERIFICATION.—The Secretary shall not accept for review any supplemental information or comments on a petition unless the party submitting such information or comments does so in written form and the subject document is signed and contains the following verification: "I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about _____. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.", with the date on which such information first became known to the party and the names of such persons or organizations inserted in the first and second blank space, respectively.

(2) EXHAUSTION OF ADMINISTRATIVE REMEDIES.—

(A) FINAL AGENCY ACTION WITHIN 150 DAYS.—The Secretary shall be considered to have taken final agency action on a petition if—

(i) during the 150-day period referred to in paragraph (1)(F), the Secretary makes a final decision within the meaning of section 10.45(d) of title 21, Code of Federal Regulations (or any successor regulation); or

(ii) such period expires without the Secretary having made such a final decision.

(B) DISMISSAL OF CERTAIN CIVIL ACTIONS.—If a civil action is filed against the Secretary with respect to any issue

raised in the petition before the Secretary has taken final agency action on the petition within the meaning of subparagraph (A), the court shall dismiss without prejudice the action for failure to exhaust administrative remedies.

(C) ADMINISTRATIVE RECORD.—For purposes of judicial review related to the approval of an application for which a petition under paragraph (1) was submitted, the administrative record regarding any issue raised by the petition shall include—

(i) the petition filed under paragraph (1) and any supplements and comments thereto;

(ii) the Secretary's response to such petition, if issued; and

(iii) other information, as designated by the Secretary, related to the Secretary's determinations regarding the issues raised in such petition, as long as the information was considered by the agency no later than the date of final agency action as defined under subparagraph (2)(A), and regardless of whether the Secretary responded to the petition at or before the approval of the application at issue in the petition.

(3) ANNUAL REPORT ON DELAYS IN APPROVALS PER PETITIONS.—The Secretary shall annually submit to the Congress a report that specifies—

(A) the number of applications that were approved during the preceding 12-month period;

(B) the number of such applications whose effective dates were delayed by petitions referred to in paragraph (1) during such period;

(C) the number of days by which such applications were so delayed; and

(D) the number of such petitions that were submitted during such period.

(4) EXCEPTIONS.—

(A) This subsection does not apply to—

(i) a petition that relates solely to the timing of the approval of an application pursuant to subsection (j)(5)(B)(iv); or

(ii) a petition that is made by the sponsor of an application and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

(B) Paragraph (2) does not apply to a petition addressing issues concerning an application submitted pursuant to section 351(k) of the Public Health Service Act.

(5) DEFINITIONS.—

(A) APPLICATION.—For purposes of this subsection, the term “application” means an application submitted under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act.

(B) PETITION.—For purposes of this subsection, other than paragraph (1)(A)(i), the term “petition” means a request described in paragraph (1)(A)(i).

(r) POSTMARKET DRUG SAFETY INFORMATION FOR PATIENTS AND PROVIDERS.—

(1) ESTABLISHMENT.—Not later than 1 year after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall improve the transparency of information about drugs and allow patients and health care providers better access to information about drugs by developing and maintaining an Internet Web site that—

(A) provides links to drug safety information listed in paragraph (2) for prescription drugs that are approved under this section or licensed under section 351 of the Public Health Service Act; and

(B) improves communication of drug safety information to patients and providers.

(2) INTERNET WEB SITE.—The Secretary shall carry out paragraph (1) by—

(A) developing and maintaining an accessible, consolidated Internet Web site with easily searchable drug safety information, including the information found on United States Government Internet Web sites, such as the United States National Library of Medicine's Daily Med and Medline Plus Web sites, in addition to other such Web sites maintained by the Secretary;

(B) ensuring that the information provided on the Internet Web site is comprehensive and includes, when available and appropriate—

(i) patient labeling and patient packaging inserts;

(ii) a link to a list of each drug, whether approved under this section or licensed under such section 351, for which a Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations), is required;

(iii) a link to the registry and results data bank provided for under subsections (i) and (j) of section 402 of the Public Health Service Act;

(iv) the most recent safety information and alerts issued by the Food and Drug Administration for drugs approved by the Secretary under this section, such as product recalls, warning letters, and import alerts;

(v) publicly available information about implemented RiskMAPs and risk evaluation and mitigation strategies under subsection (o);

(vi) guidance documents and regulations related to drug safety; and

(vii) other material determined appropriate by the Secretary;

(C) providing access to summaries of the assessed and aggregated data collected from the active surveillance infrastructure under subsection (k)(3) to provide information of known and serious side-effects for drugs approved under this section or licensed under such section 351;

(D) preparing and making publicly available on the Internet website established under paragraph (1) best practices for drug safety surveillance activities for drugs

approved under this section or section 351 of the Public Health Service Act;

(E) enabling patients, providers, and drug sponsors to submit adverse event reports through the Internet Web site;

(F) providing educational materials for patients and providers about the appropriate means of disposing of expired, damaged, or unusable medications; and

(G) supporting initiatives that the Secretary determines to be useful to fulfill the purposes of the Internet Web site.

(3) POSTING OF DRUG LABELING.—The Secretary shall post on the Internet Web site established under paragraph (1) the approved professional labeling and any required patient labeling of a drug approved under this section or licensed under such section 351 not later than 21 days after the date the drug is approved or licensed, including in a supplemental application with respect to a labeling change.

(4) PRIVATE SECTOR RESOURCES.—To ensure development of the Internet Web site by the date described in paragraph (1), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

(5) AUTHORITY FOR CONTRACTS.—The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subsection.

(6) REVIEW.—The Advisory Committee on Risk Communication under section 567 shall, on a regular basis, perform a comprehensive review and evaluation of the types of risk communication information provided on the Internet Web site established under paragraph (1) and, through other means, shall identify, clarify, and define the purposes and types of information available to facilitate the efficient flow of information to patients and providers, and shall recommend ways for the Food and Drug Administration to work with outside entities to help facilitate the dispensing of risk communication information to patients and providers.

(s) REFERRAL TO ADVISORY COMMITTEE.—Prior to the approval of a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 351 of the Public Health Service Act, the Secretary shall—

(1) refer such drug to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee; or

(2) if the Secretary does not refer such a drug to a Food and Drug Administration advisory committee prior to the approval of the drug, provide in the action letter on the application for the drug a summary of the reasons why the Secretary did not refer the drug to an advisory committee prior to approval.

(t) DATABASE FOR AUTHORIZED GENERIC DRUGS.—

(1) IN GENERAL.—

(A) PUBLICATION.—The Commissioner shall—

(i) not later than 9 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, publish a complete list on the

Internet Web site of the Food and Drug Administration of all authorized generic drugs (including drug trade name, brand company manufacturer, and the date the authorized generic drug entered the market); and

(ii) update the list quarterly to include each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug during the preceding 3-month period.

(B) NOTIFICATION.—The Commissioner shall notify relevant Federal agencies, including the Centers for Medicare & Medicaid Services and the Federal Trade Commission, when the Commissioner first publishes the information described in subparagraph (A) that the information has been published and that the information will be updated quarterly.

(2) INCLUSION.—The Commissioner shall include in the list described in paragraph (1) each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug after January 1, 1999.

(3) AUTHORIZED GENERIC DRUG.—In this section, the term “authorized generic drug” means a listed drug (as that term is used in subsection (j)) that—

(A) has been approved under subsection (c); and

(B) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the listed drug.

(u) CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.—

(1) IN GENERAL.—For purposes of subsections (c)(3)(E)(ii) and (j)(5)(F)(ii), if an application is submitted under subsection (b) for a non-racemic drug containing as an active ingredient (including any ester or salt of the active ingredient) a single enantiomer that is contained in a racemic drug approved in another application under subsection (b), the applicant may, in the application for such non-racemic drug, elect to have the single enantiomer not be considered the same active ingredient as that contained in the approved racemic drug, if—

(A)(i) the single enantiomer has not been previously approved except in the approved racemic drug; and

(ii) the application submitted under subsection (b) for such non-racemic drug—

(I) includes full reports of new clinical investigations (other than bioavailability studies)—

(aa) necessary for the approval of the application under subsections (c) and (d); and

(bb) conducted or sponsored by the applicant; and

(II) does not rely on any clinical investigations that are part of an application submitted under subsection (b) for approval of the approved racemic drug; and

(B) the application submitted under subsection (b) for such non-racemic drug is not submitted for approval of a condition of use—

- (i) in a therapeutic category in which the approved racemic drug has been approved; or
- (ii) for which any other enantiomer of the racemic drug has been approved.

(2) LIMITATION.—

(A) NO APPROVAL IN CERTAIN THERAPEUTIC CATEGORIES.—Until the date that is 10 years after the date of approval of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph, the Secretary shall not approve such non-racemic drug for any condition of use in the therapeutic category in which the racemic drug has been approved.

(B) LABELING.—If applicable, the labeling of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph shall include a statement that the non-racemic drug is not approved, and has not been shown to be safe and effective, for any condition of use of the racemic drug.

(3) DEFINITION.—

(A) IN GENERAL.—For purposes of this subsection, the term “therapeutic category” means a therapeutic category identified in the list developed by the United States Pharmacopeia pursuant to section 1860D–4(b)(3)(C)(ii) of the Social Security Act and as in effect on the date of the enactment of this subsection.

(B) PUBLICATION BY SECRETARY.—The Secretary shall publish the list described in subparagraph (A) and may amend such list by regulation.

(4) AVAILABILITY.—The election referred to in paragraph (1) may be made only in an application that is submitted to the Secretary after the date of the enactment of this subsection and before October 1, 2022.

(v) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997.—

(1) ANTIBIOTIC DRUGS APPROVED BEFORE NOVEMBER 21, 1997.—

(A) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) shall be eligible for, with respect to the drug, the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable.

(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

(i) APPLICATION.—An application described in this clause is an application for marketing submitted under this section after the date of the enactment of this subsection in which the drug that is the subject

of the application contains an antibiotic drug described in clause (ii).

(ii) ANTIBIOTIC DRUG.—An antibiotic drug described in this clause is an antibiotic drug that was the subject of an application approved by the Secretary under section 507 of this Act (as in effect before November 21, 1997).

(2) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997, BUT NOT APPROVED.—

(A) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) may elect to be eligible for, with respect to the drug—

(i)(I) the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; and

(II) the 5-year exclusivity period referred to under clause (ii) of subsection (c)(3)(E) and under clause (ii) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; or

(ii) a patent term extension under section 156 of title 35, United States Code, subject to the requirements of such section.

(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

(i) APPLICATION.—An application described in this clause is an application for marketing submitted under this section after the date of the enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

(ii) ANTIBIOTIC DRUG.—An antibiotic drug described in this clause is an antibiotic drug that was the subject of 1 or more applications received by the Secretary under section 507 of this Act (as in effect before November 21, 1997), none of which was approved by the Secretary under such section.

(3) LIMITATIONS.—

(A) EXCLUSIVITIES AND EXTENSIONS.—Paragraphs (1)(A) and (2)(A) shall not be construed to entitle a drug that is the subject of an approved application described in subparagraphs (1)(B)(i) or (2)(B)(i), as applicable, to any market exclusivities or patent extensions other than those exclusivities or extensions described in paragraph (1)(A) or (2)(A).

(B) CONDITIONS OF USE.—Paragraphs (1)(A) and (2)(A)(i) shall not apply to any condition of use for which the drug referred to in subparagraph (1)(B)(i) or (2)(B)(i), as applicable, was approved before the date of the enactment of this subsection.

(4) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding section 125, or any other provision, of the Food and Drug Ad-

ministration Modernization Act of 1997, or any other provision of law, and subject to the limitations in paragraphs (1), (2), and (3), the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 shall apply to any drug subject to paragraph (1) or any drug with respect to which an election is made under paragraph (2)(A).

(w) DEADLINE FOR DETERMINATION ON CERTAIN PETITIONS.—The Secretary shall issue a final, substantive determination on a petition submitted pursuant to subsection (b) of section 314.161 of title 21, Code of Federal Regulations (or any successor regulations), no later than 270 days after the date the petition is submitted.

(x) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

(1) IN GENERAL.—In the case of an application under subsection (b) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), the term “date of approval” shall mean the later of—

(A) the date an application under subsection (b) is approved under subsection (c); or

(B) the date of issuance of the interim final rule controlling the drug.

(y) CONTRAST AGENTS INTENDED FOR USE WITH APPLICABLE MEDICAL IMAGING DEVICES.—

(1) IN GENERAL.—The sponsor of a contrast agent for which an application has been approved under this section may submit a supplement to the application seeking approval for a new use following the authorization of a premarket submission for an applicable medical imaging device for that use with the contrast agent pursuant to section 520(p)(1).

(2) REVIEW OF SUPPLEMENT.—In reviewing a supplement submitted under this subsection, the agency center charged with the premarket review of drugs may—

(A) consult with the center charged with the premarket review of devices; and

(B) review information and data submitted to the Secretary by the sponsor of an applicable medical imaging device pursuant to section 515, 510(k), or 513(f)(2) so long as the sponsor of such applicable medical imaging device has provided to the sponsor of the contrast agent a right of reference.

(3) DEFINITIONS.—For purposes of this subsection—

(A) the term “new use” means a use of a contrast agent that is described in the approved labeling of an applicable medical imaging device described in section 520(p), but that is not described in the approved labeling of the contrast agent; and

(B) the terms “applicable medical imaging device” and “contrast agent” have the meanings given such terms in section 520(p).

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Additional Views

During the Committee's consideration of this bill, concerns arose about the bill's approach and possible unintended consequences of enacting it as drafted. This legislation accordingly warranted further deliberation by this Committee before any additional legislative action.

GUY RESCHENTHALER,
Member.

